

## Industry-Led Tiered-Pricing or Country-Led, Real Equitable Access – the Global Fund’s Task Force Proposal Gets Worse Instead of Better

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Mark Dybul, Executive Director of the Global Fund to Fight AIDS, Tuberculosis and Malaria has been shopping a proposal for a blue ribbon task force to create a new global framework on tiered-pricing since November 2013. His first proposal was launched at Global Fund meetings in November and was summarized as follows in an Executive Director’s Report to the Board:

### **Tiered pricing to expand access**

2.20 As part of our move to better accommodate and adjust our business model according to the different stages of the development continuum, we have developed a new multi-agency initiative to help expand access to essential health commodities through a multi-tiered pricing framework. Increasingly, people living in low- and high-income countries have access to such products, but those in the middle can be left without access. Co-sponsored by the World Bank, UNDP, UNICEF, UNITAID and GAVI, we will also be actively collaborating with WHO. The work will create a blue-ribbon Task Force of leading multidisciplinary experts, which will develop a framework for multiple pricing- and royalty tiers for health commodities to help ensure a sustainable marketplace and maximize availability across countries of all income levels.

This sketch of the proposal was apparently based on an undated concept paper developed by Jesse Bump, *Tiered Pricing to Expand Access to Essential Medicines and Vaccines*. That paper in turn referred to the call for new pricing models growing out of the 2011 vaccine-related Pacific Health Summit organized with strong support of the Gates Foundation and the pharmaceutical industry.<sup>1</sup> Dybul’s industry-centric proposal prompted a strong civil society critique at the Global Fund Board meeting followed by a public questioning of the proposal at ICASA in South Africa.<sup>2</sup> Civil society Board representatives at UNITAID sent a critical inquiry to the UNITAID secretariat in response to UNITAID having been listed as a supporter of the initiative, and Doctors Without

<sup>1</sup> A list of sponsors can be found at <http://www.pacifichealthsummit.org/about/sponsors/default.aspx>; a report on the Summit can be found at

<http://www.nbr.org/publications/CHA/2011PacificHealthSummitReport.pdf>.

<sup>2</sup> William New, *Concerns Raised To Global Fund Over Panel On Tiered Medicines Pricing*, IP-Watch (Dec. 10, 2013) <http://www.ip-watch.org/2013/12/10/concerns-raised-to-global-fund-over-panel-on-tiered-medicines-pricing/>; Antigone Barton, *Global Fund tiered pricing panel for ARVs, other health commodities raises questions*, Science Speaks (Jan. 6, 2014) <http://sciencespeaksblog.org/2014/01/06/global-fund-tiered-pricing-plan-for-arvs-other-health-commodities-raises-questions/>. A follow-up memo letter was sent to Mark Dybul by treatment activists on December 20, 2013; he responded by a letter dated January 29, 2014.

Borders issued a press release.<sup>3</sup> Suerie Moon, a Harvard academic, posted a short article questioning the revival of a stale tiered-pricing approach.<sup>4</sup>

Following this initial, broad-spectrum critique, on or about February 19, 2014, Mark Dybul sent out a second-draft of the concept paper based in part on responses received from listed partners, including UNITAID and UNDP. That draft has since been leaked to Knowledge Ecology International, which wrote a long trenchant criticism of the proposal summarizing the input of multiple access-to-medicines activists who had also seen the draft.<sup>5</sup> Civil society was also active during this time frame in contacting partner organizations attempting to get them to critique the tiered-pricing focus of the proposed task force and the exclusion of developing country input.

On or about March 18, 2014, a third draft of the renamed “equitable access” proposal was released to partners for further input. If anything, this third draft, the text of which is attached to this paper, is worse than the previous two drafts:

- The equitable access objectives of the Task Force are less tiered-pricing centric, but tiered pricing is still hard-wired in as the single solution that the proponents continue to champion.
- A key intervention mentioned in the second draft has been deleted, namely IP reform and increased and coordinated use of TRIPS public health flexibilities. This is an intentional exclusion and cannot be justified – overcoming IP barriers is in many circumstances to only way to increase affordability.
- Most of the proposal addresses the needs of poor people in MICs as if the problem of access to needed health products has been met in LICs, which is clearly untrue.
- The focus on “basic” medicines only is highly undesirable. The focus should be on all needed medicines, including medicines for infectious diseases, childhood diseases, neglected diseases, chronic and non-communicable diseases, etc.
- Low- and middle-income governments should be in the driver’s seat in articulating needs, solutions, and flexibilities; they are inappropriately excluded from input in the concept paper that will guide the Task Force.
- Private industry’s interests are unduly reflected in this draft and industry inappropriately has a key place on the Task Force; instead, originators and

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<sup>3</sup> Global Fund: Proposed shake-up to drug pricing framework risks middle-income countries paying more (Dec. 2, 2013) <http://www.msf.org/article/global-fund-proposed-shake-drug-pricing-framework-risks-middle-income-countries-paying-more>.

<sup>4</sup> *Is the Global Fund Heading Backwards on Access to Medicines?* PLOS Blogs (Dec. 1, 2013) <http://blogs.plos.org/speakingofmedicine/2013/12/01/is-the-global-fund-heading-backwards-on-access-to-medicines/>.

<sup>5</sup> *Resurrecting the Ghost of Høsbjør Past: Global Fund seeks to establish global framework on tiered pricing enforced by WTO Rules*, KEI Blog (March 14, 2014), <http://keionline.org/node/1979>. All the presentations that had been made at the 2001 WTO Høsbjør Conference on Tiered Pricing can be found at [http://www.wto.org/english/tratop\\_e/trips\\_e/hosbjor\\_presentations\\_e/hosbjor\\_presentations\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/hosbjor_presentations_e.htm).

- generics should be excluded except with respect to consultations.
- Other listed partners have been given an illusory and bizarre option of presenting one issue that needs to be addressed as a means of ensuring their buy-in to the Task Force proposal; this is not an evidence-based way to develop a well-considered list of equitable access options.
- The idea of a WTO enforcement mechanism has been dropped but the WTO is still inappropriately listed as an interested institution.

The Global Fund's ill-conceived proposal is getting more and more industry-centric and dangerous. The proposal development process has excluded the very countries that it is intended to benefit as if they shouldn't be in the driver's seat in proposing and weighing multiple options that might be available to them. The proposal ignores all available evidence gleaned from the scale-up of HIV/AIDS treatment – namely that robust generic competition is key to affordable pricing and that countries must take advantage of public health intellectual property flexibilities in order to increase affordable access to medicines for all. The proposal continues to champion tiered pricing, which can play a minor role at best, as the predominate strategy needing global attention. Focus on this discredited strategy will undermine the Medicines Patent Pool and UNITAID's progressive market impact efforts. It will derail IP reform efforts underway in Brazil and South Africa and discredit the use of patent oppositions and compulsory licenses. And it will ultimately strengthen the hand of Big Pharma in maintaining hegemonic control over non-transparent pricing decisions imposed on low- and middle-income countries. Better options are already on the table. Middle-income countries, UNAIDS, and UNDP organized a consultation on access to ARVs in middle-income countries in June of 2013.<sup>6</sup> The BRICS are showing new resolve in adopting, using, and protecting TRIPS public health flexibilities. Indeed countries have united at the WHO in adopting a Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property.

Listed partners and countries should rebel against this ill-conceived top-down proposal and insist on a country-led process that considers the broad range of options available to countries to ensure equitable access to affordable medicines needed for all health conditions.

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<sup>6</sup> *International consultation focuses on access to HIV medicines for middle-income countries*  
(13 June 2013)  
<http://www.unaids.org/en/resources/presscentre/featurestories/2013/june/20130613brazil/>.

# Equitable Access to Basic Medicines, Vaccines and Diagnostics: Towards a Framework for Success [3/18/14]

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## Summary

Over the past decade, there has been a significant increase in access to life-saving health interventions in low- and certain middle- income countries (MICs) including diagnosis, immunization and treatment for key infectious diseases. As many low-income countries move to achieve middle-income status, they generally lose eligibility for certain global health resources reserved for low-income countries<sup>7</sup>. This has undesirable implications for access to basic health commodities. Despite their increased income, many MICs are still unable to provide, key elements that contribute to improved access, for target populations. It is a serious problem, because there are now over 100 MICs<sup>8</sup> accounting for five of the world's seven billion people;<sup>9</sup> where we also find the greatest disease burden<sup>10</sup>. Given that many people living in MICs are still poor; it is becoming a priority for donors to support the design of new approaches that increase equitable access to basic health commodities. Therefore, agreeing a new global framework to improve access to diagnostics, basic medicines and vaccines would allow a refined and feasible approach to responding to the emerging problem. Based on economic and development analysis, as well as on a principle of tradeoffs<sup>11</sup> - such a framework would identify and consider a range of access strategies acceptable to Development Partners, Multilateral Institutions, Bilateral donors, the Governments of affected countries, Civil Society and Industry. Strategies that might be considered include licensing, technology transfers, royalties, Advanced Market Commitments, creating conditions for both innovator and generic competition, and a framework for tiered pricing; all buoyed by a firm understanding of each relevant market, policy and regulatory processes, and country environments. This would be in addition to enhanced procurement and supply chain practices - (e.g. pooled procurement). Such action would help to increase equitable and high quality access. Therefore, a number of Development

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<sup>7</sup> This includes financial assistance from donors

<sup>8</sup> <http://data.worldbank.org/country/>

<sup>9</sup> Center for Global Development

<sup>10</sup> Glassman A, Sakuna Y, New Data, Same Story: Diseases Still Concentrated in Middle Income Countries. Washington DC: Center for Global Development, September 2013. <http://www.cgdev.org/blog/new-data-same-story-disease-still-concentrated-middle-income-countries>

<sup>11</sup> There are many competing access related issues that require consideration; accordingly Task Force members will likely have to make tradeoffs and agree what is essential and what is expendable in order to close access gaps in middle-income countries, a sustainable way.

**Partners (GAVI<sup>12</sup>, GFATM<sup>13</sup>, The World Bank, UNDP<sup>14</sup>, UNICEF and UNITAID) are engaging a Task Force of leading experts from the public, private and NGO sectors, to respond to the access challenge in MICs.**

**Note:** The Global Equitable Access Framework, will consider the following as key levers to improve access to basic health commodities: a) national income; b) human right-to-health<sup>15</sup>; c) equity; d) procurement and supply chain management; e) regulation; f) global and national health policy; and g) health infrastructure.

## **Background – Current Access Situation**

**Development Partners and stakeholders have been successful in increasing access to health commodities.**

Over the past decade, there has been a significant increase in access to life-saving health interventions in low- and certain middle- income countries (hereafter MICs), including diagnosis, immunization and treatment for key infectious diseases, including HIV, tuberculosis and malaria. Factors that have contributed to these achievements include: i) considerable competition - often enhanced by the entry of generic and low-cost manufacturers from the developing world; ii) the lack (until recently) of pharmaceutical product patents in many countries that enabled production of generics (e.g. India); iii) the use of flexibilities afforded under **Trade-Related Aspects of Intellectual Property Rights (TRIPS)** and used by several countries; iv) voluntary licenses issued from innovators to generics, sometimes with royalty agreements; v) tiered pricing arrangements offered by manufacturers; vi) increased predictability of long-term demand; vii) a significant reduction in the price of relevant health commodities, in particular vaccines, and HIV treatment, antimalarial treatment, and long-lasting insecticide-treated mosquito nets; viii) large scale donor funding leading to increased volume of purchases; ix) large-scale pooled procurement; and other innovative procurement approaches; x) improved national planning; xi) strengthened health systems; and xii) regulatory improvements.

**Despite significant achievements, we see a disturbing new trend in middle-income countries.**

There are now over 100 MICs<sup>16</sup>, accounting for about five of the world's seven billion people<sup>17</sup>. Using 2012 World Bank GNI<sup>18</sup> data, GNI per capita in these MICs span a very broad range of income per head, from \$1036 - \$12,615. When considering distribution of global poverty:- In 1990, more than 90% of the world's poorest people lived in countries classified as low-income. In comparison, today, 70% of the world's poorest people live in MICs<sup>19</sup>. To compound these issues, majority of the sick people in the world also live in

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<sup>12</sup>GAVI – Global Alliance for Vaccines and Immunization

<sup>13</sup> GFATM – Global Fund to Fight, Aids, TB, Malaria

<sup>14</sup> UNDP – United Nations Development Program

<sup>15</sup> affordability, availability, accessibility, acceptability and quality

<sup>16</sup> <http://data.worldbank.org/country/>

<sup>17</sup> Center for Global Development

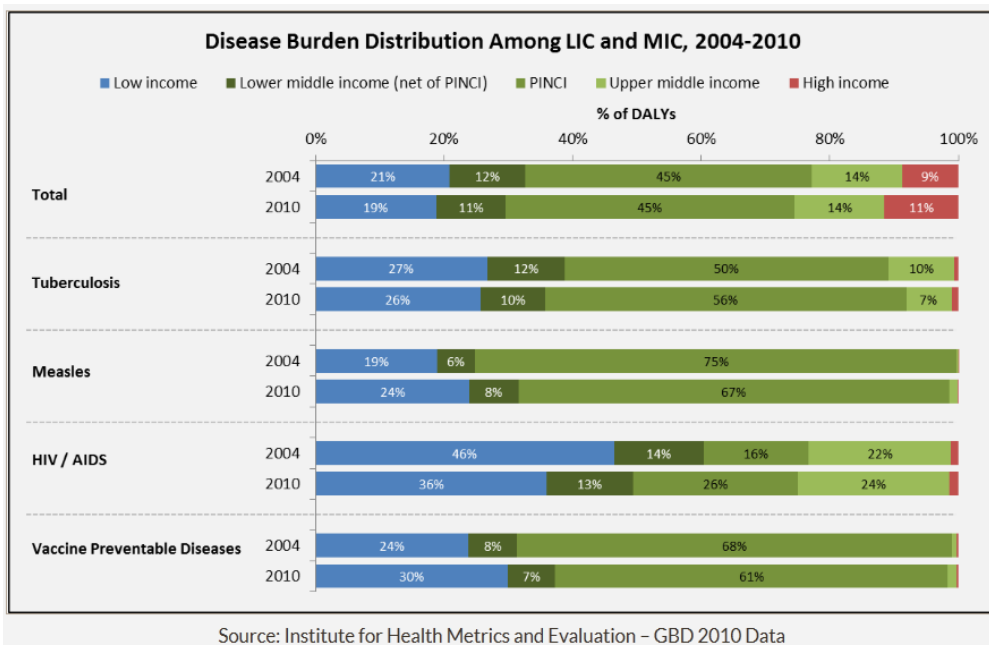
<sup>18</sup> gross national income per capita

<sup>19</sup> Berkley S, Improving Access to Vaccines through Tiered Pricing. Geneva: GAVI Alliance. March 2014.

The Lancet doi:10.1016/S0140-6736(13)62424-1. [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)62424-1/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62424-1/fulltext)

MICs<sup>20</sup>, (according to data from the Institute for Health Metrics and Evaluation (IHME), University of Washington). The implications for many MICs is that despite their overall increase in wealth, many are still unable to provide key elements that contribute to improved access, for target populations. Furthermore, access can be particularly difficult for certain innovative health products where there is often limited competition amongst suppliers. This situation is leading to a world in which low- and high-income countries have access to health commodities - but the poor in MICs are being left behind.

**Table 1: Disease Burden in Low- and Middle-Income Countries 2004-2010**



PINCI: Pakistan, India, Nigeria, China and Indonesia

**Not all characteristics and consequences of the current access trend are fully understood.**

In search of implementable solutions, the Task Force would review key characteristics and consequences of the above described situation. Members would then identify the best opportunities and options to work collectively, to close related access gaps. We hereby highlight 7 of those features and problems, to provide insight into the anticipated work of the Task Force.

Essential areas to be considered include: i) the problem of unmet need; ii – vi) (Each partner kindly please state one critical access area that requires Task Force attention

<sup>20</sup> <http://www.cgdev.org/blog/new-data-same-story-disease-still-concentrated-middle-income-countries>

here); vii) the lack of a systematic global framework on pricing for essential health commodities.

**The problem of unmet need:** Despite significant gains, much demand for life-saving health commodities remains unmet. Only 50% of HIV-positive persons in need of treatment are receiving it; only half of households in sub-Saharan Africa own one or more long-lasting bednets to prevent malaria; and much more should be done to distribute artemisinin combination therapies together with malaria diagnostic tests. Regarding vaccines, nearly one in five deaths of children younger than 5 years is still caused by a vaccine preventable disease. Further, there are more than 22 million children in the world still unimmunized against common but life-threatening diseases (as measured by a vaccine containing a third dose of diphtheria-tetanus-pertussis [DTP]).<sup>21</sup>

**Area for each Partner to please expand on the feature or issue stated on the previous page (in up to 15 lines only). Please also provide exact citations from the literature to support examples as necessary.**

**No systematic global framework on tiered pricing for essential health commodities to respond to the access dilemma:** Many MIC governments find it difficult to provide equitable access to basic health commodities, for target populations. Yet, there is no systematic global framework on pricing which might help to remedy the situation. For example, the vaccine revolving Fund of the Pan American Health Organization (PAHO) groups low-income countries such as Haiti (with GNI of \$760) together, to negotiate some of the lowest vaccine prices worldwide. A large percentage of PAHO countries are also middle-income or high-income countries with a GNI ranging between \$4085<sup>22</sup> and as much as \$18,000<sup>23</sup>. PAHO is still able to pool volumes across regions to negotiate reasonable prices for their members. MICs around the world which are not part of any organized framework agreement, may not always obtain the best price during such price negotiations. Sometimes, this results in high profile, protracted negotiations, that pit manufacturers against public health institutions and advocates, country-by-country and commodity-by-commodity.

### **Strategy for Equitable Access in Middle-income Countries**

The GAVI Alliance, the Global Fund to Fight AIDS, TB, and Malaria; the United Nations Development Programme; UNICEF; UNITAID and the World Bank jointly convene a Task Force of leading experts across diverse constituencies and from Industry - to develop a global access framework for basic health commodities.

The Task Force will explore a wide range of potential approaches to achieve that objective, recognizing that these may be different for different types of commodities. Accordingly, the analysis, will segment commodity types based on relevant access issues and analyze each separately.

<sup>21</sup> Berkley S, Improving Access to Vaccines through Tiered Pricing. Geneva: GAVI Alliance. March 2014. The Lancet doi:10.1016/S0140-6736(13)62424-1. [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)62424-1/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62424-1/fulltext)

<sup>22</sup> Berkley S, Improving Access to Vaccines through Tiered Pricing. Geneva: GAVI Alliance. March 2014. The Lancet doi:10.1016/S0140-6736(13)62424-1. [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)62424-1/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62424-1/fulltext)

<sup>23</sup> Puerto Rico - [http://en.wikipedia.org/wiki/List\\_of\\_countries\\_by\\_GNI\\_\(nominal,\\_Atlas\\_method\)\\_per\\_capita](http://en.wikipedia.org/wiki/List_of_countries_by_GNI_(nominal,_Atlas_method)_per_capita)

As part of the work of the Task Force, there is also a need to commission rigorous socio-economic analyses to gain a better understanding of ways to measure countries' ability to pay for health commodities. These could include an assessment of, for example, i) percent of the population living in poverty; ii) percent of the population with access to basic medicines and commodities, or with even more refined analysis; iii) percent of the poor with access to basic commodities and services, possibly further disaggregated by burden of disease.

Convening partners recognize the importance of maintaining incentives for Industry to invest in R&D for global health commodities.

Members will also ensure that the community builds upon existing access arrangements that work; while identifying new and practical solutions.

### **Desired Outcomes and Project Milestones**

The desired project outcome is a systematic global framework for equitable access to basic health commodities, in middle-income countries. The framework will focus on a comprehensive range of opportunities<sup>24</sup> to expand access. There are four major project milestones:

#### **Milestone 1) *Expert Task Force Convened.***

The ability to engage leading experts will be essential to the success of the project. In the first instance, the project will convene and coordinate a Task Force of about 40 leading experts in health (government officials, NGOs, advocates, representatives of patient groups, academics), economics, international law, ethics and representatives of generic and innovator pharmaceutical and vaccine companies from developed and developing countries to develop an equitable access framework. Engagement of both generic and innovator manufacturers will be important to developing a viable framework.

Task Force members will be selected based on their experience with pharmaceutical and vaccine pricing, global markets, IP, and relevant policymaking and advocacy with appropriate balance to ensure maximum representation of key stakeholders. For many of the members of the task force, the subsequent scheme developed will directly impact their country (and affected populations) or organization. It is expected that they will be the people who will influence the adoption of the recommended framework.

Where there may be knowledge gaps within the task force, members will identify potential external consultants who can engage in selected analyses. Additionally, the expert Task Force will determine which commodities are most amenable to start with within potential pilot projects and determine where such pilot projects should best be implemented. In addition to technical analysis, a collaboration infrastructure would be developed to support the large group in considering non-technical issues that often delay results from cross-sector and cross-cultural collaboration.

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<sup>24</sup>levers of access to essential health commodities



This large group would meet three times throughout this project, including at kickoff stage. A smaller working group (of 10 to 12 persons) representing key stakeholders will meet regularly and will have responsibility for managing the project, assessing progress towards the achievement of milestones, performance against objectives, and devising strategies for maximizing the dissemination and impact of the project results.

**Milestone 2) *Framework for Income Classification as basis for more equitable access***

As mentioned in M1, the Task Force will be asked to undertake the development of a framework. Essential to this undertaking will be the ability to: (1) define the parameters of the access framework (2) establish criteria for all the key elements of the framework; (3) and develop enforcement mechanisms, to ensure implementation of the framework.

The Task Force will also be empowered to explore additional or alternative mechanisms to promote equitable access to essential health commodities and to develop comprehensive approaches to foster such access.

High-level tasks and outcomes include: (1) developing an outline for the proposed access framework and identifying knowledge gaps; (2) conducting empirical (and other relevant) analyses to close those gaps; (3) actual drafting and preparation of the framework; (4) managing the dissemination of the completed draft framework for comment by external reviewers (to be determined by the full Task Force) allowing time for consultation; (5) subsequent revision and finalization; and (6) developing and implementing a public engagement plan.

**Milestone 3) *Publication of Expert Task Group's Framework for Global Access***

Once finalized, the Task Force will publish the framework in a major journal, or other open-access, public vehicle within 12 months of the onset of the work. The target group will be stakeholders involved in increasing equitable access to basic health commodities, including nation states themselves, and Industry.

**Milestone 4) *Potential Pilot Project.***

As the framework is finalized and prepared for publication, organizers and interested members will work with countries and companies to potentially pilot the framework in a limited number of specific countries by the end of the project (12 - 24 months). It is understood that for vaccines in particular, sufficient scale is required to secure optimal prices and therefore a pilot might not be required for vaccines. Still, the expert task force will include country representatives, who may express interest in pilot projects. The Task Force will collectively develop a preliminary list of countries or regional groups and manufacturers to agree access parameters within the framework for all relevant countries. Measures of success include the willingness of countries and manufacturers to engage in this undertaking coupled with the actual ability of countries to access the piloted commodities according to the established framework. The entire process will respect national legislation and international principles of public procurement.

During the project, the Task Force will conduct formal outreach to institutions such as the G20, the WTO that may have interest in the ultimate framework proposed.