

Equitable Access to Essential Medicines and Vaccines: Developing a Framework for Success

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Summary

A key aspect of increased access to health over the past decade has been the significant price reductions for health commodities achieved for low income countries. However, as some low-income countries move to achieve middle-income status, they no longer have access to the lowest prices. Yet, they cannot afford the high prices paid by high-income countries, which pharmaceutical companies tend to charge them. Given the situation, agreeing a new global framework for access amongst key stakeholders would allow a feasible and refined approach to ensuring more equitable access. Based on economic and development analysis, as well as on a principle of tradeoffs - such a framework would consider a range of pricing and access strategies acceptable to Development Partners, Governments, Civil Society and to Industry. Strategies to be considered would include licensing, royalties, Advanced Market Commitments, creating conditions for both innovator and generic competition, tiered pricing; all buoyed by a firm understanding of the relevant markets, policy processes, and country environments. This would be in addition to enhanced supply chain practice, e.g. pooled procurement. Such action would help to continue to drive prices to the lowest, sustainable levels while providing quality health products to all. Therefore, Development Partners: GAVI¹, GFATM², The World Bank, UNDP³, UNICEF and UNITAID are engaging a Task Force of leading experts from the public, private and NGO sectors, to respond to the described access challenge. On the following pages, this concept note, i) presents and ii) analyses the current access situation; iii) shares the project action plan; and iv) desired outcomes; and vi) draws attention to the milestones of the Task Force.

Background – Analysis of 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 important health programs in low- and certain middle- income countries including childhood vaccinations and treatment for key infectious diseases, including HIV, tuberculosis and malaria. A key aspect of increased access has been a significant reduction in the price of health commodities, in particular vaccinations and HIV treatment. Several factors have contributed to the price

¹ GAVI – Global Alliance for Vaccines and Immunization

² GFATM – Global Fund to Fight, Aids, TB, Malaria

³ UNDP – United Nations Development Program

reductions that some countries now enjoy. These include: i) significant competition often enhanced by the entry of generic manufacturers; ii) the lack (until recently) of pharmaceutical product patents in many countries that enabled production of generics (e.g. India); iii) the use of TRIPS flexibilities by several countries; iv) voluntary licenses issued from innovators to generics, sometimes with royalty agreements; v) tiered pricing arrangements offered by manufacturers; vi) large scale funding; vii) large-scale pooled procurement; viii) improved national planning; ix) strengthened health systems; and x) regulatory improvements.

Despite success, there is a disturbing new trend in middle-income countries.

Despite increased access due largely to lower prices that low-income countries enjoy, new countries achieving middle-income status, often do not have access to the lowest prices available to low-income countries. Likewise, middle-income countries cannot afford the prices paid by high-income countries, which the pharmaceutical companies tend to charge them. This is especially true when there is limited competition amongst suppliers in a given market. This situation, is leading to a world in which low- and high-income countries have access to health commodities but the poor in middle-income countries are being left behind. In that regard, while in 1990, 94 percent of poor people lived in low-income countries, in 2006, only 26 percent did.

Analysis: Not all characteristics and consequences of the current access situation are fully understood.

To demonstrate why it is important to address the access issue in MICs, we expand upon five characteristics of the current access situation. These are resulting consequences of the access trends. They include issues around demand, the supply side, country classification and measurement of income status, the lack of a global framework on pricing, as well as learnings from past policy processes.

Demand: Despite significant gains, much demand remains unmet. Only 50% of HIV-positive persons in need of treatment are receiving it; coverage of long-lasting bednets to prevent malaria is about 60% and artemisinin combination products penetrate less than 10% of the potential market. Key childhood vaccinations, such as pneumococcus, rotavirus, and other important vaccines are estimated in the vicinity of 10%. Coverage of other life-saving vaccines, such as hepatitis A and B and human papilloma virus, are in single digits. And tragically, 2.4 million of the 2.7 million deaths from cervical cancer that could be prevented with a vaccine occur in low- and middle-income countries.

Moreover, on the demand side, the current model of pricing for childhood vaccines, antiretroviral therapy for HIV and other commodities is flawed for several reasons: i) there is no international accepted framework for establishing pricing that provides for fair access to health commodities; it has generally been ad hoc, often relying solely on the discretion of the pharmaceutical manufacturer – this has been particularly the case for products for which there is a single supplier (e.g. patented products) ; ii) providing low-cost vaccines to low-income countries is inflexible because it does not necessarily lead to the lowest sustainable price (or price reductions over time); and iii) it gives limited decision-making power to governments. iv) In the field of HIV, new ARVs are increasingly made available in many developing countries through the licensing of patented ARVs to generic manufacturers, sometimes in exchange for a royalty. The establishment of the Medicines Patent Pool has accelerated this trend and enabled more countries to benefit and for terms to be more public-health oriented and transparent.⁴ But some middle-income countries have not been able to benefit extensively from voluntary licensing or only in certain cases. The possibility of tiered royalties has also been discussed as a possible mechanism to enable additional countries to access more affordable ARVs in a sustainable manner, while compensating the patent holder.

⁴ See WHO/WIPO/WHO, *Promoting Access to Medical Technologies and Innovation* (2012), p. 180.

Supply: On the supply side, tiered pricing exists today in both innovator and generic industries.

Country classification and measurements of income status: Many countries are moving from low- to middle-income country status. Frameworks for classifying countries, also used for setting various types of pricing strategies have emerged. However, country classification using per capita Gross Domestic Product (GDP) and Gross National Income (GNI) do not reveal the significant and growing income inequalities in middle income countries; for example the percent of the population living in poverty; and the percent of people in various income categories with access to health services and commodities. Moreover, evidence shows that, the percent of the world's poor living in low-income countries has decreased from 94 percent in 1990 to 26 percent in 2006. Further, as countries move to middle-income country status; and as they enter free trade agreements favorable pricing agreements and TRIPS flexibilities become more difficult to navigate. This means that measurements of income status, as well as the rationale that sometimes underlie manufacturer pricing policies, could benefit from reconsideration.

Global framework on pricing for MICs: There is no systematic global framework on pricing for middle-income countries, often resulting in high profile, protracted and damaging negotiations that pit pharmaceutical companies against public health institutions and advocates, country-by-country and commodity-by-commodity. For example, GAVI negotiated an initial price of USD \$7/dose with GSK for a newly developed 10-valent pneumococcal conjugate vaccine. PAHO could not obtain the same price and opted not to purchase the vaccine; while Brazil moved forward to independently negotiate with GSK for an initial price of USD \$16/dose. PAHO subsequently agreed to a price of USD \$14.85/dose. As part of that agreement, countries such as Nicaragua (per capita GDP PPP of \$3,500) pay the same price as Ecuador (GDP PPP \$8,400) or Chile (GDP PPP \$15,800). Such inequitable pricing that groups countries by such divergent GDP, let alone the inequity within countries, is highly problematic, especially when there are few suppliers serving a given market.

Past policy processes: Various policy processes have been introduced in the past to address the access to medicines issue. During this project such policy processes and the measures taken as a result, could be consulted, by the Task Force. They include a proposed framework for royalties put forward by UNDP/WHO available at: http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf. Moreover, in June 2013 an event convened by Brazil, UNAIDS, UNITAID and WHO, in collaboration with the Medicines Patent Pool, WIPO and the WTO – began to review critical challenges that middle income countries experience, in ensuring they have access to affordable and high quality HIV medicines. At that meeting, Partners made some initial recommendations on ways to address the mentioned challenges that may also be relevant for other health commodities.⁵

Strategy for Equitable Access in Middle-income Countries

The Global Alliance for Vaccines and Immunization, the Global Fund to Fight AIDS, TB, and Malaria; the United Nations Development Programme; UNICEF; UNITAID and the World Bank are joining together to consider solutions to ensure more equitable access. As previously mentioned, the goal and strategy of this project is to engage a Task Force of leading experts in relevant public and private sectors and civil society, to develop a global access framework for key health commodities. The Task Force will explore all relevant approaches to achieve that objective.

⁵ <http://www.unaids.org/en/resources/presscentre/featurestories/2013/june/20130613brazil/>

Action Plan

Analysis of the current situation around access to medicines leads to actions which stakeholders could take, to ensure more is done for those middle-income countries that are being left behind.

Maintain and expand upon current arrangements, while adopting a principle of tradeoffs - and a more nuanced access framework to achieve project goals.

The Task Force would maintain and where possible, expand on current arrangements that enable access to more affordable health commodities in low-income countries. At the same time, a principle of tradeoffs among stakeholders could be adopted to identify ways to ensure fairer access regimes for all, while creating conditions for both innovator and generic competition.

Furthermore, a more nuanced framework may be required in respect of pricing, access conditions, procurement conditions, intellectual property, licensing terms (including, for example, royalties).

Introduce more rigorous socio-economic analysis to understand income status

Review of the current access situation called for more rigorous socio-economic analysis to gain a better understanding of ways to measure income levels. These could include an assessment of, for example, i) percent of the population living in poverty; ii) percent of the population with access to essential medicines and commodities, or with even more refined analysis; iii) percent of the poor with access to essential commodities and services, possibly further disaggregated, by age or gender.

Desired Outcomes and Project Milestones

The desired project outcome is a systematic global framework on pricing for middle-income countries. In addition, there are four major project milestones.

Milestone 1) Expert Task Force.

The ability to engage leading experts will be essential to the success of the project. Preliminarily, 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 companies 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 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 pricing framework.

Additionally, convening a panel of experts that will include leaders in their fields will provide the template to learn from the past and break through with a creative approach. Moreover, 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 the 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.

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 including the number of tiers, (if tiered pricing is adopted as an aspect of the framework); (2) establish criteria for all the key elements of the framework; (3) and develop enforcement mechanisms, to ensure implementation.

There is a wide socio-economic range among middle-income countries and some have large parts of the population living in poverty. As mentioned above, it is important to account for such variations between and within countries. The Task Force will commission leading economics groups to develop sophisticated yet practical analysis of equitable frameworks for access to health commodities. Based on the models, the Task Force will develop a synthesized framework, clearly delineating elements that are global and national. A framework will not establish prices for various commodities, but it will determine processes allowing for optimal pricing between country income bands. It will also promote competition within income bands. Though centered on conditions for equitable access and access to affordable prices, the framework will also consider other elements that contribute to high commodity prices: intellectual property regulations, registration systems, taxes and tariffs that contribute to high prices, quality control failures, procurement procedures, etc.

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 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.

Milestone 4) *Pilot Project.*

As the framework is finalized and prepared for publication, organizers and interested members will work with countries and companies to pilot the framework in a limited number of specific countries by the end of the project (12 - 24 months). The expert task force will include country representatives, who may express interest in pilot projects, but the Task Force will collectively develop a preliminary list of countries or regional groups and manufacturers to agree prices within the framework. 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 vaccines and therapeutics at more affordable costs according to the established framework.

We anticipate that the framework will have lasting influence and will be considered by the G20, the World Trade Organization (WTO), or other relevant institution within 24 - 36 months of development. The Task Force will conduct formal outreach to these institutions during the project. Establishing processes to enforce a framework, likely through the WTO, will be time consuming. It will be important to implement models in the near term as global agreements are created.