

EQUITABLE ACCESS INITIATIVE

PURPOSE:

The purpose of this report is to provide a summary to the Board on the Secretariat's Equitable Access Initiative.

Part 1: Problem Definition

1.1 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 HIV, TB and malaria.

1.2 However, as many low-income countries (LICs) move to achieve middle-income status, they generally lose eligibility for certain global health resources (e.g. finance and access to low prices) reserved for LICs.

1.3 Despite increased Gross Domestic Product (GDP), many MICs are still unable to provide key elements that contribute to improved access to essential health commodities for their citizens.

1.4 There are now over 100 MICs¹ accounting for five of the world's seven billion people² where we also find the greatest disease burden³ - and where over 75 percent of the world's poor now live⁴.

1.5 Many people in such countries cannot afford to procure essential health commodities for themselves should donor/ governmental institutional frameworks be removed.

1.6 Key populations who are often marginalized or criminalized frequently experience significant challenges in accessing essential health commodities, even when governmental institutional frameworks exist.

Part 2: Why this Initiative?

2.1 There has been clear direction in development broadly, and from the Global Fund's Board to look at transition. Currently, approximately US \$2 billion per year of the Global Fund's expenditures is for health commodities. It is not possible to have transition if countries cannot afford health commodities.

2.2 As more countries move into MIC status, the issues for transition of health programs will become more acute.

2.3 The Board has also directed the SIIC to provide recommendations on the role of the Global Fund in MICs, including a public health approach. To provide maximum support to the SIIC and Board for its decision-making, a discussion by a broad range of stakeholders on the complicated issues of expanded and equitable access seems to be important.

2.4 After discussing the issue with other multilateral organizations that also procure significant quantities of health commodities, the Executive Director's Report in 2013⁵ briefly

¹ <http://data.worldbank.org/country/>; examples include Zambia, Nigeria, Pakistan, India

² Center for Global Development

³ 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>

⁴ Institute of Development Studies, UK

⁵ "Report of the Executive Director", GF/B30/03.

<http://www.theglobalfund.org/en/board/meetings/thirtieth/>

mentioned the initiative in the broader context of the development continuum and the role of the Global Fund during various stages along the continuum. An Expert Panel would examine access issues.

2.5 To facilitate a multi-stakeholder discussion of the problem and potential solutions, the Expert Panel would comprise experts from the international health community, government officials of affected countries and regions, non-governmental organizations, spokespersons of affected communities, academics, economists, representatives from the international law, and ethics sectors and from Industry (i.e. representatives of both generic and innovator pharmaceutical manufacturers). Some have questioned the engagement of pharmaceutical companies on the Panel. However, as with the inclusion of the private sector, including producers of health commodities on the Board of the Global Fund, a comprehensive discussion seems required.

2.6 The Panel would operate in an analytical manner. For example, it would review the case for developing a global access framework beyond pricing; identify and address gaps in evidence, build arguments and models to support decision options; and develop action plans to help address the problem. There would be a heavy emphasis on, and engagement of, countries – their experiences with the problem and solution, and their needs for the future. The experience of various development partners, including the co-conveners, will also be analyzed.

2.7 A key area to explore is a more refined approach to income stratification that allows for inclusion of coefficients related to health that go beyond GDP and GNI to promote equitable and inclusive health along the development continuum. Illustratively, coefficients could include percent of people living in poverty, with access to essential health commodities, etc.

2.8 The Executive Director, in error, discussed “tiered pricing”. Appropriately, there was concern about assuming one solution and an appropriate assumption that the current model of tiered pricing using current income classifications would be used. That concern has been heard. The sole purpose of the initiative is to establish a multi-sectoral dialogue to explore the problem and potential solutions. 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.

Part 3: Progress so far

3.1 Following discussions with technical and implementing partners, it was agreed that there is value in taking a broader and holistic approach to ensuring equitable access as part of inclusive health and development. Therefore, in February 2014, a draft program of work was developed, to help guide planning around the Equitable Access Initiative.

Table 1: The program of work consists of 13 stages including a tentative timeframe:

Action	Timeframe
1. Confirm interest of Chair and Vice-Chair of the Expert Panel	January 2014
2. Identify key technical partners to jointly convene the Initiative	February 2014
3. Seek input and feedback from Convening Partners to finalize concept note ⁶	Ongoing
4. Consultation with Civil Society	May 2014
5. Organize face-to-face meeting with Convening Partners as per their suggestion ⁷ . A draft concept note, draft Terms of Reference and draft composition of the Expert Panel will be circulated in advance of the meeting.	June 2014
6. Introduce the Initiative to Heads of State from Africa, Asia, Latin- and South America	tbd
7. Formally share concept note (as accepted by Convening Partners) with civil society for feedback by 1 August 2014	July 2014
8. Formally share concept note with key Suppliers of essential health commodities for feedback by 1 August 2014	July 2014
9. Incorporate feedback from all constituencies and from Industry into a revised concept note	August 2014
10. First meeting of the Expert Panel	tbd
11. Second meeting of the Expert Panel	tbd
12. Third meeting of the Expert Panel	tbd
13. Issue report for considerations by governing bodies, e.g. in countries or multilateral organizations.	tbd

Part 4: Update on Program of work

4.1 Convening Partners to the Initiative have been identified. They are: i) the Global Alliance for Vaccines and Immunizations (GAVI), ii) the Global Fund to Fight AIDS, TB and Malaria, iii) the World Bank, iv) the United Nations Development Programme (UNDP), v) the United Nations Children Fund (UNICEF), and vi) UNITAID. For legal reasons, WHO cannot participate as a co-convenor. However, the WHO Director General has agreed that WHO will serve as an observer.

⁶ A draft concept note would accompany invitations to Expert Panel members.

⁷ At this meeting Convening Partners would formally agree the project content/concept note, Terms of Reference (ToRs) and membership of the Task Force, and the overall process going forward.

4.2 The initiative will build upon important previous work achieved by Partners. An example is an intellectual property related process initiated in June 2013 by Brazil, WHO, UNITAID and UNAIDS to review critical issues that middle income countries experience, in particular those recently emerging/about to emerge into middle income country status, in ensuring they have access to affordable and high quality HIV medicines.⁸

4.3 The initiative will also build on the experiences of countries and regions, which are the central focus of the effort.

4.4 Governments, civil society and communities living with, and most affected by the three diseases will be systematically included through the program of work (as described above in Box 1) including regular stakeholder consultations.

4.5 Access levers that could be explored by the panel include:

- Economic Classification 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 improvement 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 they move along the development continuum;
- Mechanisms for technology transfer – to generic companies and to local manufactures;
- 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

⁸ <http://www.unaids.org/en/resources/presscentre/featurestories/2013/june/20130613brazil/>