

Advancing innovation to save lives

455 Massachusetts Avenue NW Suite 1000 Washington, DC 20001 ph: 202 822 0033 www.ghtcoalition.org

February 26, 2016

His Excellency Mr. Ban Ki-moon United Nations Secretary-General UN Headquarters First Avenue at 46th Street New York, NY 10017

Dear Mr. Secretary-General:

As members of the Global Health Technologies Coalition (GHTC)—a group of more than 25 nonprofit organizations working to increase awareness of the vital role health technologies play in saving lives in low- and middle-income countries (LMICs)—we would like to thank the High-Level Panel on Access to Medicines for their commitment to promoting innovation in and access to high-quality health technologies and offer the following considerations in support of the ongoing challenge to ensure that essential health tools reach the people who need them.

According to research conducted by the GHTC in a 2013 briefing paper on access to new health technologies, *Improving the affordability, availability, and acceptability of health technologies*, the World Health Organization (WHO) defines access as "a coordinated set of activities needed to ensure that the products developed will ultimately have an equitable public health impact. Achieving that impact requires products that are available, affordable, and acceptable to end users, and adopted into LMIC health systems."ⁱ Affordability means that users and buyers are able to pay the price of the product. Availability includes activities to ensure a reliable, regular, high-quality supply of the technology, and may take place at the local, national, regional, and global level. Finally, acceptability ensures that there is demand and willingness from beneficiaries, end users, health systems, and buyers to adopt the product.

Historically, the introduction of new health technologies in LMICs relied on a trickle-down approach, which assumes products developed for high-income settings will eventually be accessible to poorer populations. This structure came about partially due to the high cost of research and development (R&D), combined with a need for developers to show a return on investment in R&D, sometimes through the use of intellectual property rights to ensure sales in higher-income markets. However, the approach of waiting for new tools to eventually trickle down to vulnerable populations delays wide-scale adoption of much-needed health interventions, as opposed to developing products incorporating LMIC considerations from the start such that they do not face the same challenges to introduction.

Beginning in the 1990s, product development partnerships (PDPs), many of which are members of GHTC, and initiatives with market-shaping activities were created to support such a scale-up

approach and accelerate the development, affordability, and accessibility of new health technologies targeting poverty-related diseases and conditions. Though their primary role is to develop, not deliver, health technologies, PDPs have worked to ensure access as quickly as possible to the technologies that they and their partners develop, while maintaining quality standards. To date, PDPs' efforts have focused on accelerating product development, establishing affordable pricing and sustainable supplies, and advocating for resources and policies to enable timely product adoption at the country level.

Ultimately, many PDPs work with—and sometimes rely on—other stakeholders (e.g., nonprofit organizations, national governments, local health systems, and manufacturers) to help deliver the technologies they create to ensure that the products get into the hands of people who need them most, thus increasing access to vital health tools for populations in need. Since the creation of these mechanisms, the pipeline of products addressing the health needs of LMICs has grown substantially—including 485 technologies currently in development, 58 percent of which were developed by PDPs and other public-private partnerships.^{II}

As the Panel works to consider policy options to enhance and strengthen the promotion of innovation and access to quality medicines, vaccines, diagnostics, and other health tools, GHTC highlights the following considerations—developed on the basis of the extensive global health R&D experience of GHTC members.

- The design of a new health technology must incorporate input from the local communities and countries that will use the product. Product development funders must understand and address the needs and wants of those who will ultimately be implementing and benefiting from the product. The end users must be engaged in the identification of need, design, and development of the solution, and access plans, in order to ensure that the resulting technology has impact for those most in need.
- Achieving regulatory approval does not guarantee local access. PDPs and partners may achieve global access milestones (e.g., receiving WHO prequalification) but this does not guarantee that the technology will be accessible at the national or subnational level. A global access plan is necessary to facilitate implementation at the country level, but it is also critical to work with government officials, local providers, and communities to translate need into demand, plan for introduction, and accelerate the uptake of new technologies.
- Relying on national average income status can undermine access for the poorest populations. In many middle-income countries, the burden of disease is among poorer populations who have not benefitted from strengthening economies. Conflicting criteria used to define LMICs has complicated price negotiations as countries transition from receiving donor funds to becoming donors. For some middle-income countries, the national gross domestic product does not reflect what local populations can afford to spend on public health programming. In fact, recent research by the Center for Global Development shows that over 70 percent of the world's poor now live in middle-income countries.ⁱⁱⁱ Therefore, the poorest populations, often the most at-risk, are unable to access new technologies.
- Demonstrating a niche in the market for manufacturers is essential to incentivize their investment. Manufacturing partners must understand the added value that they bring to a market to enable them to invest time, effort, and expense to developing products for global

health diseases and conditions. They need to be able to see long-term benefits to their business while at the same time achieving the access goals outlined by the PDPs.

GHTC appreciates the opportunity to offer these comments to the High-Level Panel on Access to Medicines. For more information, please contact GHTC's Director, Erin Will Morton at <u>ewmorton@ghtcoalition.org</u> or (202) 540-4379. For more details on the GHTC's research into the role of PDPs and access, please refer to the third paper in a five volume series published on our website, <u>Briefing Paper, Volume 3: Improving the affordability, availability, and acceptability of health technologies</u>.

Sincerely,



innovating to save lives







Elizabeth Glaser Pediatric AIDS Foundation Until no child has AIDS.





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http://policycures.org/downloads/ND%20Pipeline%20Report%202015%20web.pdf

ⁱ GHTC, "Improving the affordability, availability, and acceptability of health technologies." Available from: <u>http://www.ghtcoalition.org/files/ER_GHTC_NPPD_briefing-paperVol_3_DEC2013-12-9.pdf</u>

ⁱⁱ Policy Cures. "The unrecognized revolution in global health." Available from:

^{III} Center for Global Development, "Global Health and the New Bottom Billion: What Do Shifts in Global Poverty and the Global Disease Burden Mean for GAVI and the Global Fund?" Available from: <u>http://www.cgdev.org/publication/global-health-and-new-bottom-billion-what-do-shifts-global-poverty-and-global-disease</u>