

**To:**

Amb. Deborah Birx, US Global AIDS Coordinator, U.S. Department of State, USA  
Dr. Jim Yong Kim, President, World Bank  
Dr. Tereza Kasaeva, Director, Global TB Program, WHO  
Mr. Peter Sands, Executive Director, Global Fund Against HIV, TB, TB, and Malaria  
Mr. Lelio Marmora, Executive Director, UNITAID  
Ms. Stéphanie Seydoux, Ambassador for Global Health, France  
Mr. Daniel Graymore, Head of Global Funds and Senior Representative in Geneva, DFID, United Kingdom  
Dr. Gerd Müller, Minister for Development and Economic Cooperation, Germany  
Mr. Hans-Peter Baur, Deputy Director General for Democracy, Human Rights, Social Development and Digital World, Federal Ministry for Economic Cooperation and Development (BMZ), Germany  
Ms. Amy Baker, Director General, Health and Nutrition, Global Affairs, Canada  
Ms. Marja Esveld, Senior Global Fund Program Coordinator, Ministry of Foreign Affairs, Netherlands  
Dr. Lucica Ditiu, Executive Director, Stop TB Partnership  
Kieran Daly, Deputy Director, Global Policy and Advocacy, Bill & Melinda Gates Foundation

*Please see below for cc list*

October 26, 2018

**OPEN APPEAL: URGENT NEED TO ADDRESS THE GLOBAL FUND  
PROCUREMENT CLIFF FOR TB**

Dear all,

We are writing to urge you to take prompt action following the United Nations High Level Meeting on TB to address the grave risks posed to countries that are rapidly shifting from pooled procurement of TB medicines and commodities, supported by the Global Fund to Fight AIDS, TB and Malaria (Global Fund), to national procurement.

Over the last 16 years, the Global Fund has helped to build ‘healthy markets’ for HIV, TB, and malaria by coordinating pooled procurement across countries, attracting additional manufacturers, encouraging submission to and procurement of medicines approved by the WHO Pre-Qualification Project or stringent drug regulatory authorities (SDRAs). In addition, commodities procured from the Global Fund enjoy a waiver which helps to address the common problem of pharmaceutical corporations not registering their products in all countries the Global Fund supports. Taken together, these strategies help ensure that essential, quality-assured medicines are accessible for people in need.

Donors have provided billions of dollars to create the current markets that have, in turn, facilitated access to affordable, quality-assured medicines. The success in this area has been unprecedented, but these gains are now threatened with current trends in decentralized procurement, fragile procurement systems, and market fragmentation.

An increasing number of countries are moving away from the Global Fund procurement mechanisms as a part of the implementation of the Global Fund's Sustainability Transition and Co-financing (STC) policy.

This includes eligible countries (classified as having high disease burden and low income) that are co-financing greater proportions of medical commodities, as well as countries slated for transition from future Global Fund support. Many of these countries face serious challenges with rapidly switching to national procurement systems for first- and second-line TB drugs and diagnostics.

Many of the countries affected have national procurement systems that are not designed to access international pooled procurement mechanisms, nor do they have the negotiating power to attract suppliers to bid for their tenders or secure the most affordable prices should any suppliers decide to bid. Also, many countries do not require WHO Pre-Qualification or SDRS approval to ensure continuity in quality of the products, nor are they able to efficiently issue waivers for medical commodities that have not been registered, effectively preventing participation in pooled procurement mechanisms.

Within the last six months, we have witnessed acute problems resulting from countries having to switch to national procurement systems without the necessary regulatory frameworks in place: first-line TB drug stock ruptures have occurred in Eastern Europe due to lack of registered drugs; pediatric ARV formulations stockouts in South Asia have occurred because a national competitive bidding process awarded the tender to a company that couldn't deliver the product; and stockouts of ARVs occurred in an impoverished country in West Africa that was asked to co-finance procurement beyond its capacity.

In addition to these national level problems, we are also concerned that countries leaving global pooled procurement mechanisms risks segmenting and destabilizing the fragile TB and drug-resistant TB (DR-TB) medicines market, resulting in fewer suppliers, higher prices, and a less stable supply.

**Therefore, we are urging global health actors and donors to act with a sense of collective responsibility to address the risks of reduced access to affordable quality TB medicines at the national and global levels.** We recommend:

1. The Global Fund carry out more rigorous **risk and readiness assessments** that take local procurement mechanisms into consideration, for countries facing gradual procurement co-financing, as well as countries in transition, and to make these assessments transparent and publicly available.
2. All relevant actors, including WHO, donors, affected countries, and the Global Fund act upon these assessments by **developing and/or strengthening mitigation strategies** to proactively monitor and address risks to the availability of commodities and scale up of treatment programs. These should cover high prices, quality concerns,

barriers preventing countries from accessing pooled procurement, and weak national procurement and regulatory systems and procedures.

3. All relevant actors **support national governments to adopt pro-access procurement policies**, including utilizing pooled procurement mechanisms, requiring WHO Pre-Qualification or stringent drug regulatory approval in drug tendering processes, enrolling in the WHO Collaborative Registration Procedure, and ensuring transparency throughout the procurement process.
4. The Global Fund **increase flexibility in its procurement co-financing agreements** with countries and strive to defer such agreements, where needed, until countries are able to enact necessary changes in national laws to put some of these procurement policies in place.

As members of civil society, treatment providers, and non-governmental organizations committed to the fight against tuberculosis (TB), we will continue to press for access to affordable, quality medicines and commodities.

While we have engaged constructively with the Global Fund on these issues, we believe these concerns deserve increased attention and urgent action from additional actors.

We strongly encourage the engagement of the above actors to coordinate the assessment of risks, and support of mitigating strategies in light of these concerns.

We request you to kindly direct your responses to Erica Lessem, Deputy Executive Director for Programs TAG, at [Erica.Lessem@treatmentactiongroup.org](mailto:Erica.Lessem@treatmentactiongroup.org), and Sharonann Lynch, HIV & TB Policy Advisor MSF Access Campaign, at [Sharonann.Lynch@msf.org](mailto:Sharonann.Lynch@msf.org).

Sincerely,

AIDS and Rights Alliance for Southern Africa (ARASA)  
Global Coalition of TB Activists  
Global Network of People Living with HIV (GNP+)  
Health GAP  
ICASO  
International Indigenous Working Group on HIV & AIDS  
KNCV  
LHL International  
Médecins Sans Frontières (MSF)  
RESULTS UK  
TB CAB  
TB Europe Coalition  
TB Proof  
Treatment Action Group (TAG)  
Wote Youth Development Projects (WOYDEP)

**CC list:**

Ms. Cheri Vincent, Chief, Infectious Diseases Division, USAID  
Dr. Ren Mingui, Assistant Director General for Communicable Diseases  
Dr. Gottfried Hirschall, Director of the HIV/AIDS Department and the Global Hepatitis Programme (GHP), WHO  
Dr. Suzanne Hill, Director of Essential Medicines and Health Products Department, WHO  
Amb. Eric Goosby, UN Special Envoy on Tuberculosis  
Mr. Matthew MacGregor, Senior Project Lead Sustainability, Transition and Co-financing, Global Fund  
Ms. Mariatou Tala Jallow, Senior Manager, Global Sourcing of pharmaceuticals and health products at the Global Fund,  
Dr. Brenda Waning, Chief, Global Drug Facility (GDF)  
Ms. Sarah Boulton Global Health Funds Team Leader, Global Funds Department, DFID, United Kingdom  
Mr. Jean-François Pactet, Assistant Director, Human Development, Ministry for Foreign Affairs, France  
Ms. Maurine Murenga, Communities Delegation Representative to the Global Fund Board  
Mr. Mike Podmore, Developed Country NGO Delegation Representative to the Global Fund Board  
Mr. Allan Maleche, Developing Country NGO Delegation Representative to the Global Fund Board  
Mr. Harley Feldbaum, Head of Strategy and Policy, Global Fund  
Mr. Eliud Wandwalo, Senior TB advisor, Global Fund  
Communication focal points of the Global Fund board constituencies