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MSF open letter to the Global Fund to Fight AIDS, TB and Malaria

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Dear Secretariat and Board of the Global Fund,

We are writing to you on behalf of Médecins Sans Frontières (MSF) to convey our concerns about the Global Fund's policies on allocation, co-financing, and transition, as the Board and Secretariat prepare to roll out its next funding allocations to countries.

New diagnostics and treatments have substantially improved outcomes among people with HIV, hepatitis C virus (HCV) and drug-resistant tuberculosis (DR-TB). But we fear that shifts in Global Fund policies will hinder countries from providing these innovations to patients, and limit their ability to procure - and use - quality and affordable drugs and diagnostics.

MSF urges the Global Fund to freeze implementation of transition plans until a risk assessment of its new allocation policies, strategies for procurement and transition plans has been conducted, and until a roadmap for scaling up access to optimal new diagnostics and treatments has been created.

The roadmap should include rapid, multi-functional molecular testing platforms that can diagnose TB and detect resistance to first-line TB drugs, perform viral load testing for HIV and HCV and early infant diagnosis of HIV. For treatment, the roadmap should include implementation of the World Health Organization 'test-and-start' recommendation for all people living with HIV; optimal first- and second-line antiretroviral (ARV) regimens; direct-acting antivirals (DAAs) for hepatitis C treatment; fixed-dose combinations for paediatric TB, and bedaquiline and delamanid to improve treatment outcomes among people with multi-drug resistant (MDR) and extensively drug-resistant (XDR) TB. The roadmap should also provide the necessary direct support for human resources, including community service delivery and adequate remuneration to ensure quality delivery of tools and services.

Given the constrained resource envelope available to Global Fund recipients, we also urge the Global Fund to urgently step up its ambitions in ongoing resource mobilization efforts so that it can deliver results that fulfill its potential and mandate.

The foreseen reduction in Global Fund support to certain affected regions and countries is likely to weaken national HIV and TB programmes and increase morbidity and mortality from, and onward transmission of both infections. MSF is particularly concerned about the implications of Global Fund policies on the Eastern Europe and Central Asia (EECA) region. The EECA region is home to 15 of the world's 27 high-burden countries, and has the fastest-growing HIV epidemic and highest prevalence of MDR-TB. The Global Fund's new funding model allocation methodology led to deeper funding cuts for EECA than any other region: between 2010-2013 and 2014-2017, funding was reduced by 15%. The most recent revision of the allocation methodology would leave the region facing additional cuts estimated at 40 to 50% in the next allocation period.

Countries with lower disease burdens still face significant unmet needs, and are at risk for similar funding cuts. Furthermore, many countries in sub-Saharan Africa including West and Central Africa (WCA) need additional investment to fight TB and HIV, but they may face restricted funding envelopes. In *Out of Focus,* a report about the HIV response in West and Central Africa, MSF found that most countries in the region are struggling to offer antiretroviral therapy (ART) to people living with HIV: of the 5 million people living with HIV, 76% are still awaiting HIV treatment, including 9 out of every 10 children. The Global Fund tends to be the major - and often, the only - donor that funds HIV activities in WCA countries, particularly the provision of ARVs. Any disruption or transitions in the institution's grant allocations and disbursements can have serious consequences for country programmes.

The Global Fund's Sustainability, Transition and Co-financing (STC) policy must be smart about expectations and restrictions applied to countries. Income-based thresholds for co-financing should be avoided, and appropriate strategies that take country context into consideration should be developed as a matter of urgency.

Given the national and regional barriers to generic competition and historic issues with quality and affordability, we are also deeply concerned about the risk involved with rapid transitions to national-led procurement of effective and affordable drugs and diagnostics. The Global Fund should take concrete steps in order to mitigate the harm caused by changing policies on national procurement of affordable and quality medicines and diagnostics.

Unfortunately, the 2014 Global Fund Investment Guidance for EECA was based on country income levels (GNI per capita). It advised countries to pay increasing percentages of commodities with domestic or other sources by the end of the current allocation period (end of 2017 or 2018). For example, lower-middle income countries (LMIC) were asked to pay for 60% of ARVs and diagnostics, and for 50% of second-line TB drugs. Currently, no one knows what the impact of such market-splitting will be on the price and quality of commodities.

In terms of procurement, the Global Fund has not yet produced a risk assessment and strategy to address identified risks which could emerge as countries assume responsibility for procurement of key commodities. We strongly urge the Secretariat and Board to consider the following:

- The Global Fund must provide alternatives beyond offering access to the Pooled Procurement Mechanism or Wambo, both of which are not adequate to respond to future challenges.

- The risk assessment we propose should include the potential impact of splitting the market and having separate procurement streams of potentially different quality, and consider whether and how able countries are to use TRIPS flexibilities to ensure generic competition.
- The Global Fund should help countries identify and adopt strategies to increase regional, joint, and national negotiating power well before handover to national procurement systems.
- The Global Fund should support civil society so it can play a monitoring role to ensure transparency of tenders, prices and supply.
- The Global Fund and countries moving closer to transition should jointly agree to a special 'trial period'. During this period, the Ministry of Health should provide tenders according to Global Fund model standards, and review outcomes from their tender on gaps and barriers that lead to suboptimal competition, higher prices and low participation from generic and proprietary companies. Specific attention should go to implementing national registration and importation procedures that will eliminate all regulatory barriers to the use of ARVs that were previously procured by the Global Fund. National registration of all the ARVs used in Global Fund programmes, and the possibility to issue a short-term importation waiver for new drugs and formulations must be ensured.

The Global Fund must avoid premature implementation of co-financing and transition policies that would damage services to vulnerable populations, procurement of affordable optimal tools, and scale-up plans where governments are either unwilling or unable to rapidly take over costs previously covered by the Global Fund. Accelerated transitions and hasty application of Global Fund policies may not only undermine progress, but even reverse the gains made.

While the Global Fund need to ensure its policies are conducive to scaling up access to critical services, international donors and national governments must step up their efforts to increase financial support and improve their response to the diseases as a matter of urgency.

Yours sincerely,

Jerome Oberreit
International Secretary General
Médecins Sans Frontières