

## Meeting Report

# The Global Fund at a Crossroads: Informing advocacy on Global Fund efforts in human rights, support to middle-income countries, and access to medicines

Report of a meeting of civil society experts and advocates

Barcelona, April 2015

## Key Messages

There is an urgent need to revive and re-energize civil society advocacy to hold the Global Fund accountable to its origins and founding principles. Recent changes in Global Fund policy and practice have taken it away from the country-driven character that set it apart from other aid agencies. It risks becoming less centered on rights-based strategies to support national responses to AIDS, TB and malaria. This report focuses on three areas of advocacy:

### 1) Middle-income countries

- Persons affected by the three diseases, particularly those also marginalized by criminalization and discrimination, must not be left behind because the average income of their countries has passed a certain threshold. Eligibility criteria for Global Fund support must allow for some provision of continued support where governments and other donors are not stepping up to sustain life-saving services. Unjust criminalization as a barrier to access to services must be addressed.
- Withdrawal or significant reduction of Global Fund support in a country should be based on considerations of progress toward ending the three diseases using evidence-based and rights-centered responses rather than a given national income cut-off. The Global Fund should stay engaged until countries' efforts to end the diseases can be demonstrably sustained without its support.
- Transitions to lower or no Global Fund support must be planned with meaningful participation of affected populations, coordination with all donors, and attention to civil society strengthening that may help sustain and advocate for community-led services over the long term. Anything less violates the Global Fund's human rights commitments and undermines the fight against the diseases.

### 2) Human rights

- The Global Fund should create, monitor and systematically respond to a performance indicator of the extent to which human rights components are in concept notes and in funded programs. There should also be a key performance indicator on gender and an indicator on the extent of funding for structural interventions to address gender-based violence, violations of women's property rights, and other such abuses.
- The Global Fund must build on its first steps to achieve its stated human rights goals, particularly by focusing on community systems strengthening that can lead to improved programs through better articulation of the demand for rights-centered programs and through expanding investments in such programs.
- The Global Fund should commission an independent assessment of the cost of needed human rights programs, which should inform mobilization of dedicated human rights resources.

### 3) Access to medicines

- The Global Fund must return to its earlier focus on the singular goal of ensuring the lowest-price quality medicines for all people, including the use of provisions in national laws and intellectual property agreements for the production and supply of generic medicines.
- Access to affordable medicines should be understood and advocated for by the Global Fund as a human rights commitment.
- Procurement policies and practices of the Global Fund, including any results of the work of the Equitable Access Initiative, must be subject to transparent and consultative governance. The "e-marketplace" currently being explored by the Global Fund should be rethought in light of the need to strengthen country capacity to negotiate prices, support generic competition, and acquire generic drugs.

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## I. Introduction

The Global Fund to Fight AIDS, Tuberculosis and Malaria, founded in 2002, has mobilized billions of dollars worth of assistance to programs to combat these three diseases across the world. The Global Fund was created partly to redress inadequate donor support for getting HIV combination therapy into the hands of people who needed it in Africa and other parts of the Global South. A movement of people living with HIV and advocates from both the Global South and the Global North joined to give HIV treatment access a prominent place on the world's stage. In so doing, they challenged “business as usual” in development assistance, demanding meaningful participation of and solidarity with people affected by HIV as a matter of human rights instead of top-down aid that served donors' interests most of all.

As the Global Fund embarks on a new strategy and a new era in its work and appears to be moving away from some of its founding values, it is especially urgent for civil society and representatives of populations affected by the three diseases to be heard in deliberations about the future of the institution.

In April 2015, the Open Society Foundations convened a consultation of experts and advocates concerned about the future of the Global Fund, particularly in the areas of preserving support to important programs in middle-income countries, realizing the Global Fund's human rights objectives, and the role of the Global Fund in supporting access to essential medicines. Participants included leaders of civil society organizations representing the interests of key populations affected by the three diseases as well as organizations active in country-level Global Fund processes, health service delivery, and health-related human rights advocacy and programs. This paper summarizes the deliberations of that consultation.

In the first decade of its work, the Global Fund adopted principles and practices that aligned it with the spirit of the human rights advocacy that energized global HIV movements. Unlike most donor agencies, the Global Fund committed itself to “country-driven” and “demand-driven” assistance—responding to unmet community need for services as articulated by countries themselves. It allowed country coordinating mechanisms (CCMs), the vehicle created to coordinate Global Fund proposals and grants in a country, to design programs best suited to the country's responses to the three diseases and to determine the resources needed. Moreover, it strongly urged CCMs to ensure that people at risk of and affected by the three diseases participated meaningfully in grant processes. While not succeeding everywhere, this approach was rightly seen as an important expression of solidarity with countries struggling to fight diseases of poverty and marginalization. In some countries it enabled unprecedented levels of support for programs that reached previously excluded “key populations” affected by HIV, including sex workers, people who use drugs and men who have sex with men (MSM).

Following a funding crisis after its first ten rounds of grant-making, the Global Fund board announced a new approach to making grants. The New Funding Model rolled out in 2014 assigns funding totals—ceiling amounts for grants—to countries, no longer calling on them to estimate their own needs. It uses an eligibility formula based on national income and

disease burden, which the Global Fund itself recognizes is inadequate to capture countries' needs and, moreover, disadvantages middle-income countries. The “graduation” of some middle-income countries to dramatically lower levels of Global Fund support, sometimes without evidence that governments or other donors will pick up the slack, is a central challenge to the Global Fund if it seeks to support effective disease reduction efforts.

Other changes in Global Fund policy merit scrutiny. Under its new leadership, the Global Fund has backed away from its earlier practices of supporting generic competition in the pharmaceutical marketplace and encouraging countries to make the most of flexibilities in national laws and in the World Trade Organization's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) so as to manufacture and acquire lower-cost generic medicines. This change has raised concerns that present and future procurement policies will limit or exclude options to secure the lowest possible price. Advocates in Barcelona also noted that such flexibilities are currently being eroded through other current and proposed bilateral free-trade agreements, posing a serious threat to the effectiveness of Global Fund investments in scaling up treatment.

The new funding processes followed closely the adoption by the board of the Global Fund of a commitment to human rights objectives in the Global Fund's work. An early internal evaluation of human rights-related efforts indicated that very little money was flowing to meet human rights objectives, something that must change for the objectives to be meaningful. In many countries, achieving human rights components of health programs requires technical and financial support to civil society organizations to enable them to be part of community-led interventions.

## II. Middle-income countries: Leaving behind challenging epidemics?

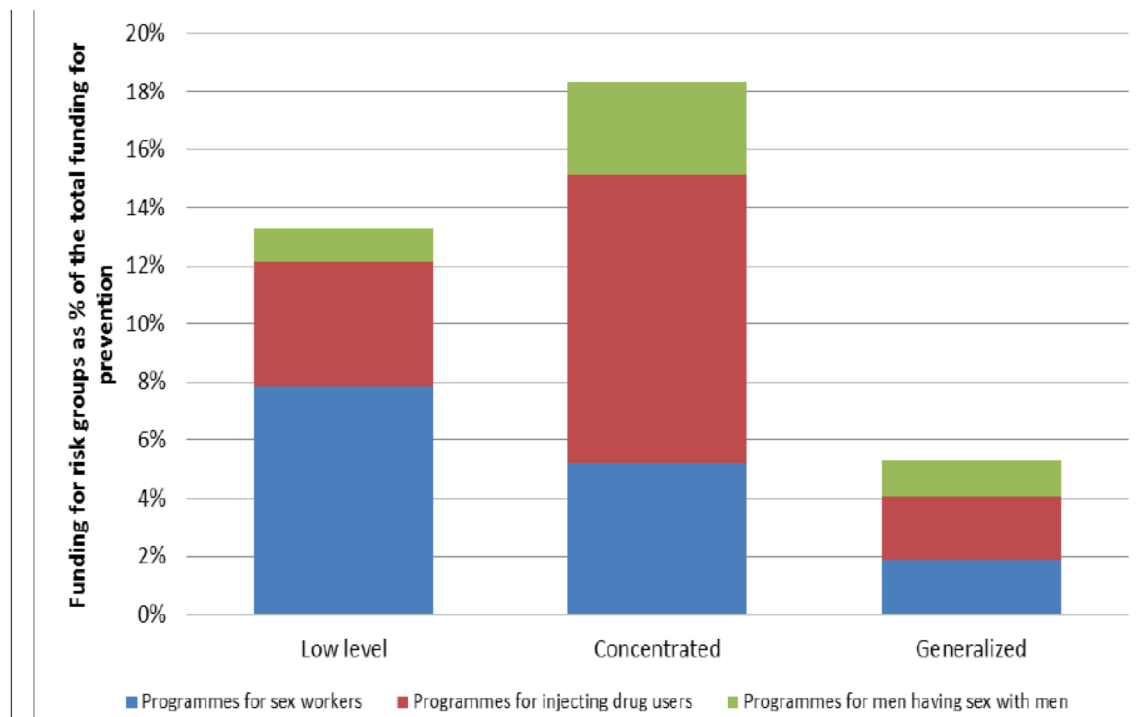
The income level of countries was always part of the Global Fund's eligibility criteria, but the New Funding Model restricted eligibility for some middle-income countries. According to its “founding principles,” the Global Fund is committed to support programs in countries with “the highest burden of disease and the least ability to bring financial resources to address these health problems.”<sup>1</sup> In addition, the Global Fund will support work in “countries and regions with a high potential for risk...,taking into account the opportunity to prevent increases in prevalence and incidence.”<sup>2</sup>

These criteria enabled some flexibility to support programs in middle-income and upper-middle-income countries, including those with, for example, HIV epidemics concentrated in “key populations.” In the first ten rounds of Global Fund grant-making—through its first decade—of HIV funding (i.e. not counting TB or malaria funding), 52 percent of funding went to 48 low-income countries, 34 percent to lower-middle-income countries, and 14 percent to upper-middle-income countries.<sup>3</sup> Low-income countries generally received higher per-capita grant amounts.

The issues of country classification by income and the need for programs for key populations affected by the three diseases are intertwined. Many of the middle-income countries supported during the first decade have HIV epidemics concentrated among sex

workers, people who use drugs, MSM, transgender women and prisoners or former prisoners. In the first ten rounds of funding, HIV grants to countries with concentrated epidemics were more likely than other countries to include prevention activities, including harm reduction programs, in their proposals.<sup>4</sup> Fig. 1 shows that for the same period key populations were the focus of HIV grants to countries with concentrated epidemics to a much greater degree than in countries with generalized epidemics. Although support for key population programs was grossly insufficient to meet the need, Global Fund grants nonetheless enabled the first scaling-up of key population HIV programs in many countries of Eastern Europe and Central Asia, as well as Thailand, Ecuador, Madagascar, Algeria and Mongolia.<sup>5</sup>

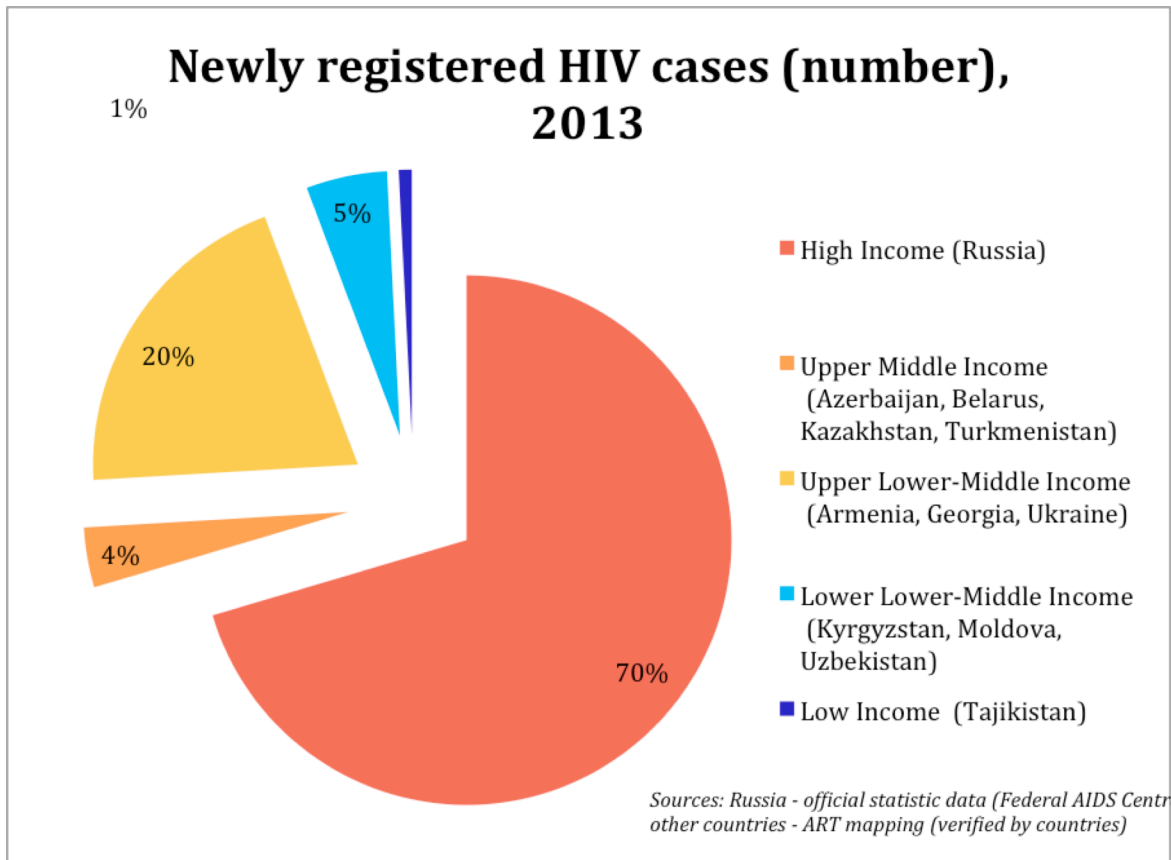
**Fig. 1. Allocation of Global Fund approved HIV funding for key populations, Rounds 1-10**



Source: Avdeeva et al., 2011.

The situation of Eastern Europe and Central Asia is particularly striking. As shown in Fig. 2, in 2013, 94 percent of new HIV cases in 12 countries of the region were in countries classified by the Global Fund as high-income or upper-middle-income and thus likely to experience severe cuts in funding or not be supported. Yet these countries have some of the world's fastest-growing HIV and tuberculosis epidemics and are in environments where support to programs for key populations from government or other donors is unlikely.

**Fig. 2. Majority of new HIV cases in E. Europe and C. Asia are in higher-income countries**



Source: A. Klepikov, International HIV/AIDS Alliance in Ukraine presentation, Barcelona meeting

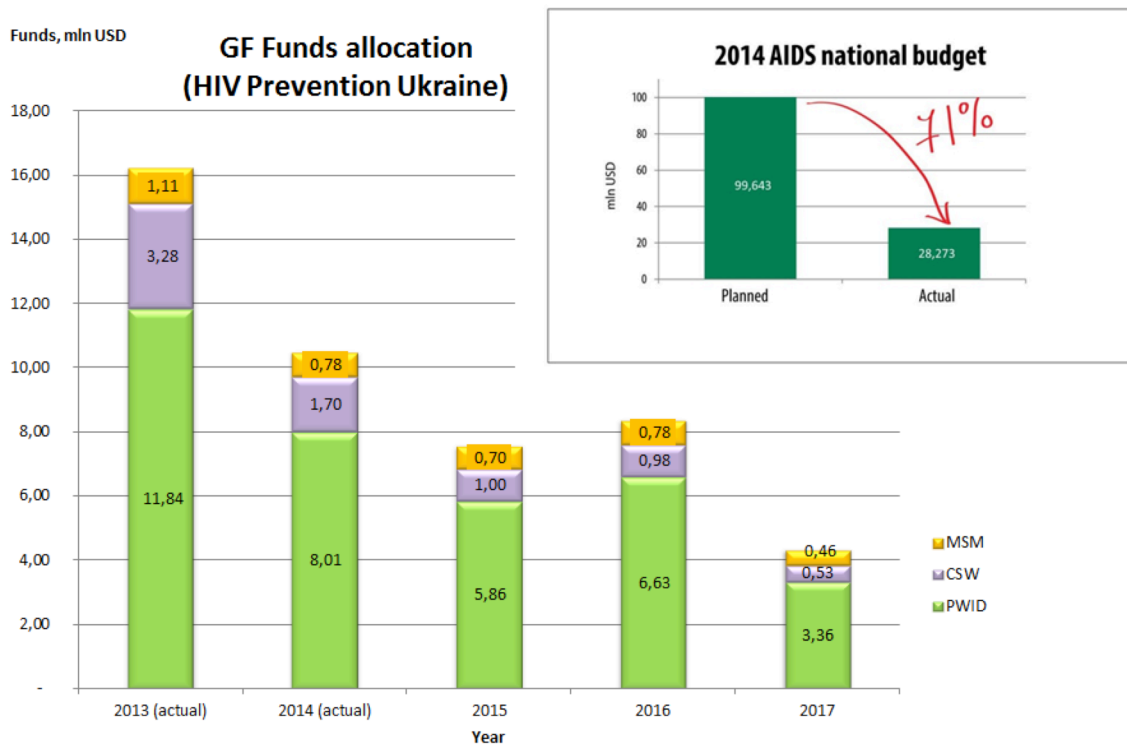
The case of Ukraine illustrates the challenge. According to Andriy Klepikov of the International HIV/AIDS Alliance in Ukraine, at the same time as government funding for HIV programs for key populations is plummeting, Global Fund support for populations of people who inject drugs, sex workers and MSM, is declining (Fig. 3). Civil society and apparently the Global Fund had understood that the government commitment to HIV programs was to be significant, but in the end the government funding in 2014 was three times less than what was pledged. Some programs were spared by significant reprogramming of some funds and the successful negotiation by the Ukrainian principal grant recipients to increase the budget in 2015. But the impact on programs in a country undergoing a period of civil and political unrest and with important concentrated HIV and TB epidemics is potentially catastrophic.

Ukraine is far from alone in its region in these respects. As noted by participants in Barcelona, Global Fund support enabled Macedonia, for example, to scale up a range of harm reduction programs over ten years, but it will be ineligible for support as of 2016. It is unclear that any analysis has been done to determine how these programs will be sustained. Similarly, Serbia, classified as an upper-middle-income country, built up HIV

prevention services from 2006 to 2014 with Global Fund support, including prison-based services. According to NGO service providers, the government has not made good on a pledge to assume funding of these programs in the face of a Global Fund exit.

In Jamaica, the Global Fund reportedly informed the government that there would be no further Global Fund support for HIV medicines, though it is not clear how such a decision is justified by Global Fund policies or values. Though the government of Jamaica had expressed willingness to take up more HIV expenditures, Jamaica is currently undergoing what some experts characterize as one of the harshest IMF-imposed austerity programs in the world.<sup>6</sup> The government has not been able to honor its earlier pledges about HIV funding, and treatment for thousands of Jamaicans is threatened. PEPFAR also made significant cuts in programs affecting Jamaica, including regional programs, at the same time as Global Fund cuts loomed.<sup>7</sup> The need for donor coordination as part of transition planning is underscored by this case.

**Fig. 3. Projected cuts in Global Fund support and government funding for prevention among key populations in Ukraine**



Source: A. Klepikov, International HIV/AIDS Alliance in Ukraine presentation, Barcelona meeting

The Development Continuum Working Group (DCWG) is a group of experts convened by the Global Fund in 2014 to reflect on the question of appropriate support to countries as they become more able to fund their own programs. The DCWG report did not make firm recommendations but reflected on factors that might ease “transitions” away from high levels of Global Fund support. It noted, for example, that increased tax revenues and the emergence of new philanthropists in countries with growing income should contribute to

cushioning cuts in external donor support. As noted in Barcelona, however, there is no evidence that various new sources of public revenue or charitable giving will add up to funding directed to programs for politically unpopular key populations.

The issue of donor support to health programs in middle-income countries, including ensuring access to essential medicines, is at the center of the work of the so-called Equitable Access Initiative, an expert group convened by the Global Fund with the participation of GAVI, WHO, other UN agencies, and UNITAID.<sup>8</sup> EAI has the goal of “building a new policy framework to better understand the health needs and constraints countries experience as they move along the development continuum.” EAI will not finish its work until well into 2016, and its deliberations so far have not been made public. As noted by the Barcelona meeting participants, advocacy directed to EAI and the Global Fund must be strong on the point that it is unacceptable to abandon support for health programs abruptly when that action is likely to result in resurgent epidemics, no matter what the income level of the country.

Participants also noted that key donors to the Global Fund, including the UK, the US and the European Union, were instrumental in pushing for accelerated transitions away from Global Fund support in some middle-income countries. Advocacy and awareness-raising targeting these donors on the importance of responsible transition or resisting ill-conceived transitions are also needed.

Whether originating from Global Fund donors or from other sources, the Development Continuum Working Group report floats a number of ideas about middle-income countries that raised concerns at the Barcelona consultation. One idea is that the Global Fund or a partner organization could offer countries “a transition instrument such as a loan/credit agreement (for 5 or 10 years)” or a “hybrid instrument” whereby donor funding would help convert loans to “more concessionary rates.” Advocates in Barcelona found this to be a dangerous idea for an institution like the Global Fund that is not constituted to be a lending agency. The DCWG also floated the idea of a “Results-Based Financing,” an approach used by the World Bank and other lenders that links continuation of financing with program results. “Results” in this case would need to be defined so as not to encourage a focus on low-hanging fruit that would leave behind key populations. Participants noted that for any new ideas on “transition”, meaningful consultation with key population groups and analysis of the impact of funding decisions on them are crucial.

Deliberations in Barcelona led to the following key points for action and advocacy:

**Responsible, rights-based transition:** Transition to lower or no funding is a process that necessarily involves meaningful consultation with affected people—a kind of “country dialogue” for transition. It should be based on clear and transparent policies and criteria with respect to the potential for other funding to pick up existing programs, including:

- consultation with PEPFAR, the UK, the European Commission and other donors;
- agreement on the minimum service needs for key populations affected by the diseases—which means not just treatment—and ways to ensure they are being reached;
- the degree to which structural barriers to services for key populations remain unaddressed;



- the political will of governments to support programs or seek other donor support and;
- an objective assessment of the consequences of cutting funding for essential programs.

Comprehensive mapping of all existing and potential donors may be useful. Where transition is necessary, planning for it must begin years before the fact. In the years ahead of transition, scaled-up funding (not reduced funding) may be necessary in order to prepare civil society to sustain the response over the long-term. **Abrupt transition without consultation with affected people and other partners is a violation of the Global Fund’s human rights principles as well as a likely path to resurgent epidemics and increased morbidity and mortality. Sustained funding for programs for key population programs may be needed for an extended period to ensure responsible transitions.**

Cuts or transitions are not inevitable: Governments should certainly be encouraged to do their part and to make good on their pledges to fund essential programs in middle-income (and other) countries. But some “transitions” should be resisted and rejected. Where there is no demonstrable evidence that government or other donors are ready to provide sustained support to life-saving programs, transition—no matter the average income level of the country—may simply not be appropriate. No matter how the Global Fund’s goals are evolving, it is unethical and unacceptable to step away abruptly from programs in cases where the lack of other support means that disease is likely to spike in affected populations. Resources must be found—perhaps in the form of an emergency fund—to sustain support until means can be put in place to avert outbreaks that will be devastating for people and for containing the diseases. These would ideally be directed toward epidemiologically critical but politically sensitive interventions, such as support for sex worker- and drug user-led interventions. Withdrawal or significant reduction of Global Fund support in a country should be based on considerations of progress toward ending the three diseases rather than a given national income cut-off.

Engagement with key donors: It would be useful for advocates with experience in reaching key donor countries such as the UK, US, and members of the European Union to increase the volume on advocacy related to rights-based transition as defined above.

Dealing with criminalization as a cause of “unwillingness to pay”: There is no responsible transition without addressing inappropriate application of criminal law and law enforcement as a cause of government and donor unwillingness to assume the costs of programs for key populations (as well as an aggravating factor for discrimination). The reality of the barriers to services faced by key populations and the importance of those barriers to the course of epidemics must be part of open debate about the future of program funding. Financial and technical support should be found for addressing these structural barriers and reaching solid terms for a social contract to reach all people with essential services.

Global Fund staying global: The Global Fund was meant to support programs in all parts of

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the world where assistance is genuinely needed to combat the three diseases. Being true to its founding would mean being in places where need arises not only from lack of resources but from government exclusion of unpopular groups from health programs.

Support for “poor countries” vs. support for people in need: The DCWG acknowledged that the World Bank Atlas income classification does not correspond to where poverty-stricken people are or where people most in need of services are kept from them by criminalization and other marginalization. The Global Fund must find eligibility criteria that are appropriate to the realities of people’s need, including the reality that programs led by affected communities may be the only way to address the needs of people most marginalized by poverty and discrimination.

Do not just add more eligibility criteria to the country income criterion: It is not yet clear how the EAI deliberations will go, but retaining the country income classification and augmenting it with other indicators is unlikely to be useful. If the Atlas criterion as an income indicator does not even adequately represent the geography of poverty, it should be abandoned, and better indicators should be found.

Civil society strengthening: The urgent need for community or civil society strengthening is not separate from the middle-income country challenge. Support for groups representing populations affected by the diseases to lead service provision may be the only way in many countries to ensure stability of services that are otherwise dropped when they are politically inconvenient. Case examples of the importance of investing in community strengthening—which is not just health system strengthening—for ensuring sustainable, high-quality health programs may be useful to develop for advocacy purposes.

Government “co-financing” and accountability: In too many cases, governments have pledged to take up elements of health programs and then failed to honor those pledges. Governments should be held accountable for these failures. There should also be more careful assessments **before** any withdrawal of funds to determine whether government co-financing pledges are backed by a real willingness to pay, as well as what amount of government support (if any) is being channelled toward socially excluded groups and human rights, rather than general programs.

Evidence for DCWG statements on new funding sources for key population programming? It is not clear if the EAI will echo the thoughts in the DCWG report about new public revenue and new philanthropy in middle-income countries. Advocates in Barcelona called on the Global Fund to show the evidence behind these statements. Statements like these can take on a life of their own if they are repeatedly mentioned in reports even if there is little or no real-life experience to back them up.

Advocating with the Global Fund’s donors: The Global Fund leadership often notes that the Fund is in a sense captive to the wishes of its donors, including the major bilateral donor agencies and large philanthropic entities such as the Gates Foundation. Advocacy efforts must include sensitizing Global Fund donors to the urgency of responsible transition and avoiding counter-productive abandonment of programs for highly affected communities.

### III. Human rights: Delivering on the commitment

The Global Fund was created as a result of human rights-centered advocacy. It deals with three diseases for which human rights violations are among the most important direct barriers to successful programs, and for which protecting, respecting and fulfilling human rights are among the most important determinants of program success. The Global Fund’s commitment to human rights should also guide its work on resolving program needs in middle-income countries and its actions related to access to medicines.

In its current strategy, it has a commitment to three strategic objectives in human rights:

- Integrate human rights considerations throughout the grant cycle
- Increase investments in programs that address human rights-related barriers to access
- Ensure that the Global Fund does not support programs that infringe human rights.

The Global Fund has taken a number of steps to implement its human rights objectives, including establishing a senior human rights staff position, an advisory human rights “reference group” of outside experts, human rights training for secretariat staff, including the Office of the Inspector General, and various guidelines for rights-oriented programming for the three diseases. It adopted a policy in 2014 by which it will generally not fund compulsory treatment in detention facilities for people who use drugs and sex workers.<sup>9</sup>

In 2014, five human rights provisions were incorporated into standard grant agreements, specifying that Global Fund-supported programs should fulfill the following criteria:

1. Ensure non-discriminatory access to services for all, including people in detention;
2. Employ only scientifically sound practices;
3. Not employ methods that constitute torture or that are cruel, inhuman or degrading;
4. Respect and protect informed consent, confidentiality and the right to privacy concerning medical testing, treatment, etc.; and
5. Avoid medical detention and involuntary isolation, which are to be used only as a last resort.

In 2014, a \$15 million special initiative was established to fund technical assistance for human rights, gender and community strengthening activities in the early stages (pre-concept note) of proposal planning. Some \$2.5 million from this initiative was given to the Robert Carr Civil Society Networks Fund for human rights activities by key population networks.<sup>10</sup> Another \$4 million will be made available in 2015-16 for regional “platforms” led by civil society, meant to help NGOs understand the Global Fund and facilitate access to technical support on human rights, gender and community strengthening.<sup>11</sup> Participants in the Barcelona meeting noted the limited scope of this support—in the pre-concept note stage of proposal planning only—and the limited funds.

A “Removing Legal Barriers” (RLB) module was also developed as part of the New Funding Model “template” by which countries can include in their proposals the following

activities: legal environment assessments and law reform; legal literacy and legal aid; training for police and other officials and health care workers on rights issues; policy advocacy on rights; and community-based human rights monitoring.<sup>12</sup> It was hoped that the having a well defined module of this kind would both encourage the development of these interventions and allow investments in them to be tracked. An earlier review of human rights interventions in Global Fund grants in 2010-2012 found that only a small number of countries included such components and a small amount of money was involved, but it was noted that it was difficult with the previous funding templates to track these activities.<sup>13</sup> A 2015 report to the Global Fund board noted that of 119 concept notes approved by the TRP under the NFM, 72 percent identified human rights-related barriers to health services, but only 10 percent included an RLB funding request.<sup>14</sup> However, the \$8 million in RLB funds requested in indicative funding<sup>15</sup> and over \$9 million in “above-indicative” support was an increase over pre-NFM requests.

In Barcelona, participants who were part of CCM discussions noted that human rights interventions are sometimes discussed in the early part of proposal planning, but seeing that they survive as budgeted components of signed grant agreements is often challenging. Participants also noted that even when the CCM includes civil society representatives who are competent human rights advocates, they often don’t understand the community strengthening and human rights measures that can be proposed for Global Fund support. “Community strengthening” is too often interpreted by CCMs as “health system strengthening” only. More support is needed to ensure that the demand for human rights and community strengthening activities is compellingly expressed and leads to effective programs.

In April 2015, the Global Fund formally launched a human rights complaint mechanism whereby anyone can report human rights violations in Global Fund-supported services related to the five human rights provisions in the grant agreements (noted above).<sup>16</sup> Telephone, e-mail and web-based channels to the Office of the Inspector General (OIG) of the Global Fund have been established for this purpose. Advocates in Barcelona, who knew of this mechanism before the official announcement, generally noted that it was limited in being *ex post-facto* and unclear in exactly what the Inspector General would be able to do to redress violations. It was suggested that this complaints procedure should not divert attention from the need for stronger support for community strengthening and ensuring meaningful participation of key populations and human rights groups in CCM processes.

There are discussions underway with rights and advocates and the OIG about the possibility of making proactive decisions to steer funds to human rights programs to address concerns raised through the complaints mechanism or to remedy situations in partnership with relevant UN and national human rights bodies. These were seen as welcome developments by advocates in Barcelona.

In the next few years, the Global Fund must show that it takes human rights seriously in all aspects of its work. It must show concretely that it bases its work on the uncontroversial idea that respecting the rights of people affected by and at risk of HIV, TB and malaria is not just useful but essential for health services to be effective. In so doing, it would be true to its origins—the powerful human rights-centered advocacy that brought it into being.

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In the view of participants at the Barcelona meeting, the following measures are priorities for advocacy and action:

Retain human rights objectives with small modification: Urge the Board of the Global Fund to retain the three human rights objectives in the current strategy, with a small modification of the objective about integration of human rights in the grant cycle, that is: Integrate human rights considerations throughout the grant cycle **and in policies and policy-making processes (of the Global Fund)**. In addition, human rights should not be treated as an isolated, “stand-alone” objective. Additional strategic actions on human rights should be included under strategic objectives for (a) impact and (b) health and community systems strengthening.

Non-CCM grants and community strengthening: The Board and Secretariat should recognize explicitly that fulfilling human rights objectives in some cases requires support to entities other than the CCM, particularly where the CCM demonstrably excludes key affected populations from planning and programming. There should be policy guidance in the Global Fund both for criteria for determining when non-CCM grants are needed and appropriate, and for supporting non-CCM coalitions in their role as grant recipients.

CSS objective: With respect to the existing strategic objectives of the Global Fund, there should be a new strategic action under objective 1 related to community systems strengthening (CSS), given the critical importance of strong civil society capacity to implement human rights programs as part of maximizing the impact of Global Fund investments.

Dedicated funding for human rights: While the \$15 million special initiative is appreciated, it is small and narrow in scope, being focused only on building capacity of civil society organizations to engage in pre-concept note processes. **The Global Fund should with urgency commission an independent expert assessment—with meaningful participation of civil society and technical partners—of the human rights initiatives needed in key countries and what they would cost.** This assessment would form the basis for advocacy with the Global Fund’s donors to ensure that dedicated funding for human rights programs will be available, an essential condition for effective and sustainable health interventions. Appropriate mechanisms to channel dedicated funding to effective human rights programs should be actively explored. This should include a review of existing ones such as the Robert Carr Civil Society Networks Fund as well as others.

Prioritize regional windows or funding opportunities: Proposed human rights programs often get blocked at the country level because of political sensitivities around human rights in government-dominated CCMs and the low capacity of human rights and key population organizations to manage the burdensome requirements involved in Global Fund application and negotiation processes, among other reasons. The Global Fund should expand regional funding windows with a specific mandate to use them to increase support for the kinds of human rights programming that gets blocked for political and capacity-related reasons in country grants.

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Creating demand for human rights programs: The \$15 million special initiative on technical assistance for developing human rights programming was useful but limited. Fulfilling the human rights objectives requires ensuring that civil society and key population representatives are meaningfully engaged in country dialogue, country note preparation and other stages of proposal development; that they and other members of the CCM understand the RLB component and other human rights and community strengthening measures that the Global Fund supports; and that they have the capacity to advocate for these components. In addition, there should be an avenue for seeking non-CCM support if the CCM rejects needed human rights approaches or excludes key population concerns.

Middle-income countries and human rights: Eligibility decisions regarding programs in middle-income countries should be at the top of the human rights advocacy agenda for the Global Fund. Transition that is not responsible, including transition in countries where there is no evidence that government or other donors are ready to take up the slack, is counter to the Global Fund's human rights objectives. Transition processes should especially be designed to leave open the possibility of Global Fund support for human rights activities over a long period even when other funding has been reduced. It will be the key populations in MICs who will face ongoing violations and denial of human rights and be most adversely affected by the withdrawal of Global Fund support that is, because of that hostile environment, less likely to be replaced by government funding or support from other donors.

Human rights performance indicators: There should be a performance indicator for the extent to which human rights components are in concept notes and eventually in funded programs, and it should be clear who is accountable for this outcome. If legal environment assessments are performed as part of Global Fund grants, the Fund Portfolio Managers (FPM) should follow up to urge the CCM to take into account the results of those assessments in future programming. The Global Fund should also develop rigorous monitoring procedures with respect to the five human rights provisions in grant agreements and should not rely only on the reactive complaints procedure for this monitoring.

Human rights capacity/expectations of secretariat staff, TRP, LFA: The human rights capacity of the secretariat should be increased, possibly through (1) more staff with human rights as an explicit and central focus of their work as part of the rights group in CRG, and (2) human rights-related tasks added to the job description and performance indicators for FPM and some staff of the Office of the Inspector General. FPMs should be supported to assess country-level human rights issues and facilitate development of human rights programs. With respect to the Technical Review Panel (TRP), there should be clear criteria for what constitutes human rights expertise in its work, and the TRP should always include several members with that expertise as a central element of their professional work. In addition, it would be useful for the local fund agents (LFA), who are the Global Fund's "eyes and ears" in countries for monitoring of flows of funds and accounting, to be able to do basic monitoring of the five human rights provisions in grants.

Gender issues and human rights: Gender-based violations of human rights need to be more explicitly linked to the Global Fund's human rights strategy leading to increased funding for structural interventions to address issues such as gender-based violence and violation

of women’s property and inheritance rights. The Global Fund should also consider a key performance indicator on gender. Advocates in Barcelona were aware that expert and community consultations on gender in the Global Fund strategy were currently under way and agreed that all efforts should be made to ensure that the gender dimensions of human rights are elevated in the new strategy.

Technical partners and human rights: The “technical partners” of the Global Fund, UN agencies working on any aspects of the three diseases, especially UNAIDS, WHO and UNDP—all of which have human rights mandates and in-country presence and often serve on CCMs—should do more to ensure a focus on human rights components of Global Fund proposals and programs. The Global Fund should consider formal memoranda of understanding and perhaps some level of support to these agencies to systematize this role.

Greater transparency of Global Fund policy-making as a matter of human rights: Transparency is inherent in the idea of rights-centered policy-making and grant-making in the Global Fund. The EAI, for example, illustrates a policy-making process crucial to the future of rights-based programming at the Global Fund that lacks transparency and adequate consultation with affected populations. Representatives of the advisory groups for key populations and human rights that the Global Fund has established should be involved in policy-making as much as possible.

Global Fund as human rights advocate: Fulfillment of the Global Fund’s human rights objectives is most likely if the Global Fund uses its stature in the global health arena to be an advocate for rights-centered health programs and program planning processes. A strong advocacy stance by the Global Fund leadership for the public health and human rights importance of community-led programs for key populations and for access to affordable medicines for all (see next section) is especially crucial.

#### IV. Access to medicines: Global Fund backsliding compared to the early years

A global advocacy movement for access to HIV medicines in the late 1990s and 2000s helped many countries to make the most of flexibilities in the rules of the agreement on Trade-Related Aspects of Intellectual Property (TRIPS) of the World Trade Organization, especially in procuring affordable generic medicines. The Global Fund was created in part as a result of this advocacy and was meant to mobilize donor resources for medicines for the three diseases. As a principal supporter of purchases of medicines and other supplies, it is inevitably an important player in the global protection and fulfilment of the human right to affordable essential medicines.

**The Guide to Global Fund Policies on Procurement and Supply Management of Health Products** (June 2012) states that: *Recipients will use their best efforts to apply national laws and applicable international obligations in the field of intellectual property including the flexibilities provided in the Trade-related Aspects of Intellectual Property Rights (TRIPS) agreement and interpreted in the Doha declaration in a manner that achieves the lowest possible price for products of assured quality.* (para 3.3)

The Global Fund was born of human rights-centered advocacy. Access to medicines is central to the pursuit of the right to health and as such is not and should not be separate from the Global Fund’s commitment to human rights. Being true to its founding would entail that the Global Fund promote its own existing policies on intellectual property and clearly articulate its commitment to affordable medicines as a matter of human rights.

Before its last change of leadership, the Global Fund articulated publicly its support for using TRIPS flexibilities to improve access to generic medicines and its concern about free-trade agreements that might tighten patent barriers.<sup>17</sup> Under its current leadership, however, the Global Fund has not demonstrated a strong commitment to encouraging generic competition, which is the most effective strategy for bringing down the price of medicines. This change has coincided with a more difficult environment for securing price reductions from generic competition. Since the period of price reductions on first-generation antiretrovirals, such factors as increased patenting, patent-holders’ pricing of drugs out of reach of most people who need them, and limits on voluntary licenses have made the struggle for affordable essential medicines more difficult than before. Simultaneously, the flexibilities under TRIPS ostensibly secured through advocacy at the WTO have too often proved challenging to use in practice, and are being eroded through the adoption of “TRIPS-plus” provisions in various bilateral and regional trade agreements.

In addition to turning away from its advocacy for generic competition, the Global Fund in recent years has moved toward strategies based on collaboration and long-term supply contracts with brand-name and generic producers that are unlikely to result in the lowest possible prices. The Global Fund procurement team is developing a new “market-shaping” strategy to replace the one approved by the GF board in 2011, but without the benefit of the Market Dynamics Advisory Board that previously brought some level of independent oversight and expertise to this area of work. Participants in the Barcelona meeting expressed concern that in the absence of a clear policy on access to medicines and intellectual property rights and with apparent back-sliding on support for country efforts to protect and expand generic competition, the new market-shaping strategy of the Global Fund will not necessarily be geared to sustainable price reductions as its central goal. It was noted that in this sense the **Global Fund appears to wish to portray access to medicines as a technical issue rather than the political and human rights issue that it is.**

The Global Fund now conducts its procurement activities under the program area “P4i” or Procurement for Impact. P4i is characterized by establishing collaborative relationships with producers and suppliers, including long-term contracts for guaranteed volume levels with selected preferred suppliers.<sup>18</sup> As noted in Barcelona, while there could be some advantages to these types of centralized arrangements, it is far from clear that they will result in the lowest possible prices for medicines.

In addition, the Global Fund board in November 2014 endorsed a secretariat proposal for the development of an “e-marketplace” that would centralize procurement as a web-based platform for a wide variety of health program-related purchases—a “kayak.com price comparison tool for medicines, diagnostics and nets,” as described by the Global Fund’s Executive Director, Mark Dybul.<sup>19</sup> At the time of the board discussion, a number of representatives of program implementers expressed concern that this system would



concentrate procurement control in the hands of the Global Fund secretariat without building procurement capacity at country level.<sup>20</sup> These concerns were echoed in Barcelona. The Global Fund has signaled that it would like to share the “e-marketplace” more broadly as a procurement platform for health supplies beyond those of Global Fund programs, but again this idea raises a concern about creating a platform for promoting industry-driven price segmenting schemes, rather than building country capacity in procurement and price negotiation for health programming. It was also noted that, contrary to the “kayak.com” analogy, it is not possible for users of the e-marketplace to see price comparisons or to see the prices being offered to other buyers. Experts in the meeting also noted that the e-marketplace does not flag if a generic version of the medicine is available and does not include information that would enable countries to see what they would save by purchasing at the lowest available price.

Concerns were also expressed about whether the Global Fund might be in a position to undermine the work of UNITAID. UNITAID was created in 2006 to increase access to medicines and diagnostics for HIV, TB and malaria especially in low-income and lower-middle-income countries, including by using interventions in the market to increase competition. UNITAID has retained a strong focus on encouraging generic competition and other measures that result in price reductions, explicitly addressing patent and other market barriers. Participants in the Barcelona meeting expressed concern that the UK, an important Global Fund donor, is pushing the Global Fund to take over some of the functions of UNITAID, which might over time result in a watering down of UNITAID’s essential aim of using all tools and methods available to overcome patent barriers to lower the price of medicines and diagnostics.

In the establishment in 2013 of what would eventually become the Equitable Access Initiative, the Global Fund leadership may have showed its hand in a particularly revealing way. Mark Dybul at first announced the formation of a “blue-ribbon panel” to look at industry based tiered pricing of medicines as a “solution” for access to medicines in middle-income countries that are “graduating” from donor support.<sup>21</sup> Following an extensive outcry from civil society, the idea of a tiered pricing focus of the expert group was withdrawn by Dybul, and EAI was said to have a larger mandate to look at all possible solutions to sustainability of access to medicines. At the Barcelona meeting, one expert suggested that it is likely tiered pricing is still at the center of EAI discussions. Another observer said that countries fear that the “e-marketplace” could be a window for tiered pricing.

In 2014, the Global Fund also ventured into a new effort on quality of medicines by driving the formation of the Global Steering Committee (GSC) on quality assurance.<sup>22</sup> The GSC has the goal of “harnessing the collective capabilities and innovations of major health development institutions to combat falsified, substandard, stolen and diverted medicines and other health products.”<sup>23</sup> As noted at the Barcelona meeting, it is not clear why medicine quality, for which there are numerous oversight bodies, including WHO, has become a central concern of the Global Fund. Some advocates raised concerns that the GSC could become another forum to push harmful policies that conflate generic medicines with low-quality medicines as has been seen in anti-counterfeiting legislation in Kenya—undermining the case for generics.<sup>24</sup> This seems to be one more move on the

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Global Fund's part that risks playing into the hands of industry and is not centered on improved affordability of medicines.

As discussed in Barcelona, the Global Fund's market-shaping and P4i actions and rhetoric tend to obscure the fact that the medicines market is not a functioning market in the classic sense. Especially in the case of newer medicines, production is dominated by a few producers who can use legal protections from competition to set exorbitant prices that render medicines a luxury item. The Global Fund's current procurement activities seem unconcerned with why medicines are so expensive in the first place or the underlying politics of the price of medicines. Rather, in suggesting that technical fixes to the current market can solve the challenge of affordability of medicines, the Global Fund does a disservice to countries, especially middle-income ones, that badly need the assistance of a powerful international institution to help them negotiate the legal, technical and political challenges of securing access to medicines.

Participants in the Barcelona meeting agreed strongly that **it is time to pressure the Global Fund to reclaim its commitment to use all the tools at its disposal to ensure the lowest-price medicines for all people as the center of all of its procurement activities and reflections on the "development continuum."** Civil society needs to reclaim the "market shaping" narrative and emphasize this central goal. Above all, advocates should not be mystified by all the market jargon, but rather must demand transparency and clarity of purpose. Points for advocacy and action in this area are the following:

Lowest possible prices for all as policy and foundational value: The Global Fund must not stray from its founding ideas and must relocate its procurement strategy clearly around the goal of ensuring the lowest-price quality medicines for people in all countries. Actions in the area of "market-shaping", e-marketplaces and "Procurement for Impact" that have any other focus are not acceptable. If the EAI is guided by any other goal, it is misguided. The Global Fund should be guided by the principles of its own procurement guidelines which strongly promote the use of TRIPS flexibilities (see text box above) and its earlier "market-shaping" commitments that focused on using all legal tools and mechanisms to negotiate for the lowest possible prices, pushing for optimal use of TRIPS flexibilities and encouraging competition in all situations. The "e-marketplace" needs to be rethought in view of the possibility that it may undermine countries' ability to negotiate prices and acquire generic medicines.

Transparent and consultative governance: That the Global Fund has veered into potentially industry-friendly procurement strategies without adequate consultation or transparency compounds the problem. An independent advisory group on procurement should be re-established with representation of program implementers from countries of all income levels and civil society experts on access to medicines. Policies such as the e-marketplace and all aspects of P4i should be reviewed in consultation with this independent group and the Human Rights Reference Group of the Global Fund. The Global Fund risks losing credibility as an institution working for better health outcomes for poor and marginalized people if it continues to formulate procurement actions and policies without transparency and accountability.

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Building country capacity: The Global Fund should use its considerable resources and influence to help countries navigate the hard politics of access to medicines. Countries may not need a centralized e-platform for all purchases, but they certainly need assistance in understanding how generic competition is undermined and how it might be encouraged by actions at country and international levels. Many middle-income countries are paying much more for medicines than they need to, even with the reality of constrained generic competition. Addressing such cases should be a high priority for the Global Fund.

Equitable Access Initiative: The EAI should hear the voice of civil society and feel pressure to keep its focus on strategies that result in the lowest possible prices of medicines in all situations. The EAI's work continues through 2016, enabling advocacy to be mobilized. If it is promoting tiered pricing, this position should be brought out into the open and subject to the scrutiny of civil society.

Leave medicine quality to WHO: The Global Fund should not expend its limited financial and human resources on quality assurance, which has the potential to play into the hands of industry and undermine access to generic medicines. Civil society previous fought this battle and won in a few cases; it may need to be fought again.

Formalize access to medicine as part of human rights strategic goals: The Global Fund should formally state clearly that it understands access to affordable medicines as a fundamental right. The human rights mechanisms that have been established to advance the strategic objectives on human rights should be reviewed with an eye toward formal inclusion of access to medicines outcomes.

## V. Conclusions

Participants at the Barcelona meeting were reminded that civil society advocacy around Global Fund policies and processes has resulted in some important gains. Even in countries with hostile environments and aggressive criminalization of key populations, it has been possible—not nearly often enough but at times—to enable meaningful participation of key population representatives in Global Fund processes. Some instances of community strengthening—again not nearly enough—have resulted in community-led programs that would not have happened without Global Fund support to civil society efforts.

But advocacy for a Global Fund that is true to its origins has flagged since the early years, and the current leadership appears to need a stern reminder of the founding values of the institution. The “how” of organizing national, regional and global advocacy around these points is beyond the scope of this document, but the “what” is becoming clear. Without concerted and well informed advocacy in the areas of support to middle-income countries, human rights and access to medicines, the Global Fund risks repudiating its own history, undermining its investments and damaging its stature as a leader in global health. Furthermore, the Global Fund's ambitious strategy to end the epidemics by 2030 will be a pipe dream without a reinvigoration of commitments in these three key areas.

## Endnotes

<sup>1</sup> Global Fund to Fight AIDS, Tuberculosis and Malaria. *The framework document of the Global Fund to Fight AIDS, Tuberculosis and Malaria*. Geneva, 2002, p 7.

<sup>2</sup> Ibid.

<sup>3</sup> O Avdeeva, JV Lazarus, MA Aziz, R Atun. The Global Fund's resource allocation decisions for HIV programmes: addressing those in need. *Journal of the International AIDS Society* 14:51, 2011 (open access).

<sup>4</sup> Ibid.

<sup>5</sup> Ibid., p 8.

<sup>6</sup> See, e.g., D Francis, "As Obama visits, new report says IMF program is crushing Jamaica's economy," *Foreign Policy*, 8 April 2015. At: <http://atfp.co/1GjvVn3>

<sup>7</sup> G Spaulding, "Uncertainty looms as US pulls funding from HIV programmes," *The Gleaner Jamaica* 5 September 2014. At: <http://jamaica-gleaner.com/gleaner/20140905/lead/lead7.html>

<sup>8</sup> See Equitable Access Initiative online presentation, at <http://www.theglobalfund.org/en/equitableaccessinitiative/>.

<sup>9</sup> Global Fund. Global Fund calls for end to compulsory treatment (press statement), Geneva, 26 November 2014. At: <http://bit.ly/1AM8C2T>

<sup>10</sup> Global Fund. Community, Rights and Gender report (33<sup>rd</sup> meeting of the Global Fund Board). Doc. no. GF/B33/09, March 2015.

<sup>11</sup> Ibid.

<sup>12</sup> Ibid., para 113.

<sup>13</sup> Ibid., paras 110-111.

<sup>14</sup> Ibid., para 114.

<sup>15</sup> Under the NFM, "indicative" funding is the ceiling amount assigned to the country according to the Global Fund's eligibility formula based on country income and disease burden. CCMs have the possibility of competing for "incentive" funding above the indicative total if they have compelling activities to propose. See Global Fund, "The Global Fund's New Funding Model," Geneva, April 2013.

<sup>16</sup> Global Fund, "Global Fund launches human rights complaints procedure" (media release), Geneva, 27 April 2015.

<sup>17</sup> See, e.g., Global Fund, "Global Fund strategy aims to help shape market and ensure sustainability of AIDS treatment," Geneva, 26 May 2011. At: <http://bit.ly/1BJ8Um4>

<sup>18</sup> See "Procurement for impact (P4i)" at <http://www.theglobalfund.org/en/p4i/>.

<sup>19</sup> L Gelfand. E-marketplace endorsed as centrepiece of Global Fund's emergent sourcing strategy. *Global Fund Observer*, issue 256, 23 November 2014.

<sup>20</sup> Ibid.

<sup>21</sup> S Moon. Is the Global Fund heading backwards on access to medicines? *PLoS Blog*, 1 December 2013.

<sup>22</sup> Global Fund, "Global Steering Committee advances efforts for quality assurance" (media statement), 23 March 2015.

<sup>23</sup> Ibid.

<sup>24</sup> Médecins Sans Frontières. The secret treaty: Anti-Counterfeiting Trade Agreement (ACTA) and its impact on access to medicines. October 2010, at: <http://bit.ly/1K8al4w>

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