

# ← ACCESS GRANTED

A budget advocacy toolkit for  
improving access to quality and  
affordable medicines through  
Global Fund grants



make  
medicines  
affordable  
END UNFAIR MONOPOLIES

 **ITPC**  
INTERNATIONAL TREATMENT  
PREPAREDNESS COALITION

## → ABOUT ITPC

The International Treatment Preparedness Coalition (ITPC) is a worldwide network of community activists unified by our vision of a longer, healthier, more productive life for all people living with HIV (PLHIV). ITPC's mission is to enable communities in need to access optimal HIV treatment. As a grassroots movement based primarily in the Global South, ITPC is the community's voice on HIV treatment and is driven by and committed to the human rights of those most impacted by the HIV epidemic.

ITPC is a global coalition that includes eight regional networks in Africa, Asia, Latin America and the Caribbean, Eastern Europe, and the Middle East. Through its different campaigns, ITPC is committed to providing accurate and timely HIV treatment information that can improve the lives of PLHIV. Many of the tools developed under this program are also intended to be used for advocacy initiatives.

Additional information about ITPC is available at: [www.itpcglobal.org](http://www.itpcglobal.org)

## → ACKNOWLEDGMENTS

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## → ABBREVIATIONS

<b>A2M</b>	Access to medicines
<b>ACT</b>	Artemisinin-based combination therapy
<b>ARV</b>	Antiretroviral drugs
<b>CAFTA-DR</b>	The Dominican Republic-Central America Free Trade Agreement
<b>CDA</b>	Central Drug Authority in South Africa
<b>CCM</b>	Country Coordinating Mechanism
<b>CSO</b>	Civil society organization
<b>EECA</b>	Eastern Europe and Central Asia
<b>DTG</b>	Dolutegravir
<b>FDC</b>	Fixed-dose combination
<b>FLD</b>	First-line drugs
<b>HCV</b>	Hepatitis C virus
<b>HIV</b>	Human Immunodeficiency Virus
<b>IP</b>	Intellectual property
<b>KPI</b>	Key performance indicator
<b>LAC</b>	Latin America and the Caribbean
<b>LACAP</b>	Public Administration Procurement and Contracting Law in El Salvador
<b>MDR-TB</b>	Multidrug-resistant TB
<b>MENA</b>	Middle East and North Africa
<b>MoH</b>	Ministry of Health
<b>NAC</b>	National AIDS Council
<b>NGO</b>	Non-governmental organization
<b>NSP</b>	National strategic plan
<b>NTP</b>	National TB Program
<b>OST</b>	Opioid substitution therapy
<b>PAAR</b>	Prioritized above allocation request
<b>PASCA</b>	Program for Strengthening the Central American Response to HIV/AIDS
<b>PR</b>	Principal Recipient
<b>PrEP</b>	Pre-exposure prophylaxis
<b>PWID</b>	People who inject drugs
<b>RNTCP</b>	Revised National TB Control Program in India
<b>RSSH</b>	Resilient and Sustainable Systems for Health
<b>SANAC</b>	South African National AIDS Council
<b>SANPUD</b>	South African Network of People who use Drugs
<b>SAPHRA</b>	South African Health Products Regulatory Authority
<b>TA</b>	Technical assistance
<b>TenoEm</b>	Tenofovir-emtricitabine combination
<b>TRIPS</b>	The Agreement on Trade-Related Aspects of Intellectual Property Rights
<b>TRP</b>	Technical Review Panel
<b>U=U</b>	Undetectable equals untransmittable
<b>UHC</b>	Universal health coverage
<b>UNAIDS</b>	Joint United Nations Programme on HIV/AIDS
<b>UNDP</b>	United Nations Development Programme
<b>USAID</b>	United States Agency for International Development
<b>UQD</b>	Unfunded quality demand
<b>WHO</b>	World Health Organization
<b>UMIC</b>	Upper middle-income country
<b>XDR-TB</b>	Extensively drug-resistant TB

## PART 1: INTRODUCTION

The Global Fund to Fight AIDS, Tuberculosis and Malaria (hereafter referred to as the Global Fund) is a major financier of programs to address the three diseases. The fund invests more than US \$4 billion each year in more than 100 countries.

Between now and 2028, it is projected that 33 disease components (e.g. HIV, TB, malaria) in 22 countries will transition away from Global Fund grants, due to rising income status and subsequent ineligibility.<sup>1</sup> Many others face reduced allocations as the Global Fund shifts its focus towards higher burden, lower income countries. Achieving long-term change and our goal of affordable medicines for all requires sustained investment.

Global Fund transitions require adequate foresight and planning. It is critical to embed sustainability considerations in national strategies, grant design, and program delivery.

In the context of transition preparedness, certain activities may be more strategic than others for promoting a just and equitable health system, as well as the long-term sustainability of Global Fund investments. This toolkit shares information, guidance and examples for three types of such activities:

- Activities related to intellectual property (IP)
- Activities related to procurement and access to medicines (A2M)
- Activities related to health budget advocacy for domestic funding

This toolkit is primarily aimed at civil society and community actors, especially those who represent their constituencies as members of Global Fund Country Coordinating Mechanisms (CCMs). Additional audiences may include members of writing teams that are developing Global fund funding request and transition work plan. The toolkit is geared towards all developing countries, though examples are drawn primarily from middle-income countries that are currently faced with imminent Global Fund transition.

The main objective of this toolkit is to influence Global Fund funding requests and transition work plans to include activities to improve access to quality and affordable medicines. The toolkit may also be used to advocate for such priorities in National Strategic Plans, Investment Cases, and technical support plans for multilateral partners such as the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the United Nations Development Programme (UNDP). It is not a comprehensive nor technical guide on issues related to IP, A2M or health budget advocacy. Instead, a series of useful resources is provided in Part 10 for onward reading.

To develop this toolkit, a desk review was performed to scan the most recent Global Fund funding requests and transition work plans for existing IP, A2M and health budget advocacy activities. Global Fund policies, guidelines and assessments were also reviewed. Thirteen experts from around the world were consulted, shaping the content and direction of the toolkit.

## PART 2: WHY THIS TOOLKIT?

Advocating for the inclusion of activities to improve access to quality and affordable medicines in Global Fund grants is important for many reasons. It will improve national responses by increasing treatment coverage, saving money, and reducing government dependence on funding partners for key program areas. It will also help achieve the Global Fund's strategic objectives, ensuring that the near \$40 billion it has invested since 2002 yields lasting results. Lastly, it is critical for sustaining community activism, since there have been dwindling resources for this work in recent years.

### IMPROVING NATIONAL RESPONSES

Access to quality and affordable medicines is a human right. Activities aiming to improve access to more affordable generics, tackle supplier monopolies, and increase the number and pace of new registrations are critical for increasing treatment coverage and reducing costs. Funding treatment with domestic budget lines is critical to sustain these gains. Around the world, Global Fund investments have supported such efforts:

- ➡ Only 5% of people who need treatment for multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB have access to newer and more efficient drugs (Delamanid and Bedaquiline), partly because of the high price of these medicines, and partly because these medicines are not yet registered for therapeutic use in some countries.<sup>2</sup> In June 2019, the Global Fund supported TB activists from 10 countries to convene in **UKRAINE** to discuss advocacy strategies to transition to new DR-TB treatment regimens in the Eastern Europe and Central Asia region.
- ➡ Modelling in **SOUTH AFRICA** estimates that full rollout of dolutegravir (DTG) could treat 800,000 more people living with HIV than the status quo (over four years) – and with more than US \$200 million in savings.<sup>3</sup> The first government tender for generic dolutegravir has been awarded, with rollout starting in July 2019. This process was relatively quick, thanks in part to Global Fund-supported treatment activists calling for the fast-track approval of generic producers.
- ➡ Modelling in **THAILAND** showed that despite its high cost, sofosbuvir-based regimens for the treatment of Hepatitis C (HCV) had greater quality adjusted life years gains compared with the current treatment, therefore associated with lower lifetime costs and more favorable health outcomes. The results of this study have been used in policy discussion which resulted in the recent inclusion of sofosbuvir in the Thailand's Universal Health Coverage (UHC) benefit package.<sup>4</sup> In 2017, the Global Fund's Technical Review Panel (TRP) approved Thailand's proposed activities for a Hepatitis C Advisory Board and community-led dialogues for HCV treatment.





*"If we get a generic substitute for lopinavir/ritonavir, this one case itself will be able to close the treatment gap. \$18 million comes each year for procurement of that medicine. If we get generics for that, we will only spend \$5-\$6 million instead. We should take the angle of closing the treatment gap and making the Global Fund grants more sustainable."*

**Treatment Activist in UKRAINE**

## ACHIEVING GLOBAL FUND OBJECTIVES

The vision of the Global Fund is for countries to sustain disease programs and move towards UHC as they transition from donor support. To do this, countries must (among other things) evaluate dynamics in key product markets, remove legal and policy barriers to services, and increase domestic resource mobilization.

The Global Fund's Strategy 2017-2022 has several key performance indicators (KPIs) related to the objective of this toolkit. For example, it tracks:

- ➡ The availability of medicines (KPI 6b)
- ➡ The stable supply of key quality-assured health products (KPI 12a)
- ➡ Domestic investments in key populations and human rights programs (KPI 9c)

As of May 2019, progress towards achieving targets for these three KPIs shows mixed results (Table 1).<sup>5</sup> Implementing this toolkit can help improve these outcomes.

**Table 1. Global Fund Progress Towards Achieving Key Performance Indicators**

Global Fund KPI	Target	Progress (as of May 2019)
KPI 6b: Percentage of health facilities with tracer medicines available on the day of the visit	15% reduction of non-availability for diagnostics and tracer medicines	Supply chain target reached at portfolio level for diagnostics. TB first line drugs (FLDs), HIV FLDs with Malaria FLDs are close to the target. However, individual country results vary significantly.
KPI 12a: Percentage of a defined set of products with more than three suppliers that meet Quality Assurance requirements	100% (by 2019)	69% – Low volumes of pediatric products in particular, present challenges to maintain more than three suppliers.
KPI 9c: Percentage of upper middle-income countries (UMICs) that report on domestic investments in key populations and human rights programs	100% over the 2017-2019 period	47% of UMICs with Board approved grants have reported on domestic investments in both key population and human rights programs (although 82% reported on key population investment)

As countries transition, many are shifting from Global Fund-supported mechanisms to national processes for the purchase of medicines and diagnostics for the three diseases. Sometimes called the “procurement cliff”, there is evidence that if this happens without adequate reforms to laws and policies first, access to medicines can be negatively affected. Specifically, the procurement cliff refers to three main risks<sup>6</sup>:

- **Affordability:** Purchasing medicines using national processes – as opposed to the Global Fund’s pooled procurement mechanism – reduces competition among suppliers and leaves countries vulnerable to paying higher prices.
- **Quality:** While medicines purchased with Global Fund support must meet international standards for quality, safety and efficacy, most national purchasing processes do not have such stringent quality assurance requirements.
- **Supply:** Global Fund procurement circumvents the issue of corporations not registering products in ‘unattractive’ markets. As countries transition, not all of them efficiently issue import waivers for unregistered medicines and diagnostics.
  - For example, **ARMENIA** released a national tender for first-line TB medicines, which failed because no company responded to the tender, resulting in a stock-out. This occurred despite the fact that risks of failed tenders for HIV and TB drugs due to lack of registration were identified in Armenia’s Global Fund transition readiness assessment.

The Global Fund Strategy (2017-2022) also commits the Global Fund to support all countries that apply for grants to include and scale up programs to remove human rights-related barriers to health services. Achieving this objective depends on countries’ ability to monitor and/or reform laws, regulations and policies, including those that create human rights-related barriers to accessing medicines.



*“This is the time when people who inject drugs (PWID) should constantly be looking if programs are cost-effective, if they can be brought to scale by the government, and whether the programs are supported by structural changes like law reforms. These things are key to the survival of PWID programs in the long term. If we go to the CCM and we are doing opioid substitution therapy (OST) at high cost and without changing the policies and laws, those programs will be dropped since government will not prioritize spending”*

GLOBAL FUND SECRETARIAT representative



## SUSTAINING COMMUNITY ACTIVISM

Nearly all experts consulted for this toolkit agreed that funding activities to improve access to quality and affordable medicines is shrinking. This negatively affects treatment activists' ability to do much-needed work in their countries. Global Fund investment in these priorities is therefore all the more critical.

According to those consulted, the following activities should be prioritized for inclusion in Global Fund funding requests and transition work plans for the 2020-2022 funding cycle:

- Patent law reviews, to assess the inclusion of public health flexibilities
- Technical assistance to operationalize the flexibilities
- Procurement reviews
- Monitoring the patent system and preventing low quality patents from being granted through oppositions and revocations
- Support for advocacy to routinely use the right of compulsory licenses, as necessary
- Advocacy support for civil society to oppose adoption of TRIPS+ measures
- Network strengthening of PLHIV networks and networks of TB survivors
- Mobilizing and empowering communities by investing to strengthen their advocacy
- Treatment literacy, including IP, procurement and analysis of legal barriers
- Advocacy to reduce the price of Bedaquiline and Delamid, tackling monopolies
- Advocacy to reduce the price of commodities, including reagents and consumables for viral load tests
- Advocacy for increased access to quality and affordable medicines in the context of treatment as prevention and "undetectable equals untransmittable (U=U)" campaigns
- Communications activities to improve community awareness of IP issues
- Legal literacy and legal services
- Support for affected communities to participate meaningfully in legal and policy change processes, as well as processes to review and update treatment guidelines
- Conducting Legal Environment Assessments and proposing improvements to laws
- Development of advocacy tools, including inventories of IP laws in priority countries
- Policy dialogues and advocacy with government officials
- Price reduction and treatment optimization, including targets to reduce drug prices
- Establishing social contracting mechanisms for civil society organizations (CSOs)
- Preparing CSOs to work with government
- Training for CSOs, joining them to national actors and lawyers
- Monitoring of pooled purchasing
- Support for CSOs to be part of national strategy development, including modelling
- Mapping timelines and key stakeholders and understanding the regulatory process

Activists will need to be strategic with the framing of these activities, to increase the likelihood that these can be included – in part or in full – in Global Fund grants.

## PART 3: POLICIES AND POLITICS

### UNDERSTANDING GLOBAL FUND POLICIES

Several of the Global Fund's strategies, policies, guidelines, instructions and technical briefs contain useful information on how activities to improve access to quality and affordable medicines can and should be included in its grants. It is important to underpin your advocacy with an understanding these policies and what they say. Civil society and community actors must hold the Global Fund accountable for what it says it will do.

Table 2 provides a brief overview of some of the key Global Fund policy documents, and their relevant provisions on improving access to quality and affordable medicines.



**COMMUNITY TIP:** Civil society and community activists are encouraged to reference the policy documents and relevant text in Table 2 during oral and written interventions at the CCM, as well as in funding requests and transition work plans. Doing so may help provide convincing rationale for including activities to improve access to quality and affordable medicines in Global Fund grants.

**Table 2. Global Fund Policies on Access to Quality and Affordable Medicines**

Global Fund Document	Relevant Text
Investing to End Epidemics: The Global Fund Strategy 2017-2022 (April 2016) <sup>7</sup>	Objective 4b is to "Support countries to use existing resources more efficiently and to increase domestic resource mobilization" (Page 34).  Objective 4c is to "Implement and partner on market shaping efforts that increase access to affordable, quality-assured key medicines and technologies" (Page 35).
Guide to Global Fund Policies on Procurement and Supply Management of Health Products (October 2018) <sup>8</sup>	"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 [TRIPS] agreement and interpreted in the Doha declaration in a manner that achieves the lowest possible price for products of assured quality." (Page 4)
The Global Fund Sustainability, Transition and Co-financing Policy (April 2016) <sup>9</sup>	"Planning a transition from Global Fund support takes time and resources. In many countries this involves addressing complex issues such as changing legislation to allow for the public sector to contract with non-public sector providers such as civil society organizations, effectively supporting domestic advocacy for health spending, and improving procurement processes and access to ensure that countries can purchase key commodities such as second line ARVs and MDR TB drugs at efficient prices" (Page 5).

Global Fund Document	Relevant Text
Operational Policy Manual v. 2.23 (October 2019) <sup>10</sup>	“During the implementation period of grants arising from the allocation, applicants should demonstrate increasing co-financing to progressively absorb costs of key program components such as human resources, procurement of essential drugs and commodities, programs that address human rights and gender related barriers and programs for key and vulnerable populations” (Page 133).
Market Shaping Strategy 2016-2021 (November 2015) <sup>11</sup>	<p>“The Global Fund also supports countries in obtaining quality-assured products at the lowest cost and supports the use of TRIPS flexibilities in compliance with national laws and international obligations to protect public health [...].The Global Fund does not prescribe how countries implement their obligations and flexibilities under TRIPS, as those decisions remain the responsibility of each country” (Page 8-9).</p> <p>“The Global Fund supports efforts to address barriers and practices that prevent access to affordable medicines by promoting generic competition in order to help reduce costs” (Page 19).</p> <p>“The Global Fund also supports the WHO’s Collaborative Registration Procedure to share information on WHO-prequalified products between the WHO Prequalification Program and national regulatory authorities. This is a key mechanism to accelerate national product registration” (Page 21).</p>
Funding Request Instructions: Tailored for Transition. Allocation Period 2020-2022 (November 2019) <sup>12</sup>	“Applicants can explain how their funding requests obtain the lowest costs for quality inputs required to provide services. They can demonstrate their effort to minimize costs of the inputs by showing that: (i) quality assured health products are budgeted at the lowest sustainable costs. [...] This can be illustrated by reduced health product costs, a strong rationale for investment in new technology or drugs, and more sustainable human resource cost” (Page 12).
Guidance Note: Sustainability, Transition and Co-financing of programs supported by the Global Fund (January 2017) <sup>13</sup>	“Consider Enabling Factors for Transition: With respect to procurement, this may include proactive planning to ensure continued access to affordable pricing for quality assured medicines and other health products needed to fight the three diseases after transition. It may also take into consideration aspects such as registration where waivers have traditionally been used and/or the use of TRIPS flexibilities, in compliance with national laws and international obligations, as a strategy for sustained access to medicines” (Page 13).
Technical Brief: Support to Effective Regulatory Systems for Procurement and Supply Management of Health products (October 2019) <sup>14</sup>	“Guiding Principles for investing in Regulatory Systems [...]. When and where appropriate, build on existing systems/processes and customize tools and approaches for strengthening medical product quality assurance to improve buy-in and acceptance from local governments and counterparts, the potential for sustainability, the scalability of health programs, and cost effectiveness from both a financial and human resource capacity perspective” (Page 5)

Global Fund Document	Relevant Text
Value for Money Technical Brief (November 2019) <sup>15</sup>	"The economy dimension of value for money can be strengthened by considering improvements in various areas such as program planning, procurement, financial management, and health services delivery. Applicants are encouraged to give a strong justification when input prices have not been minimized. However, paying lower prices at the expense of inferior quality or lower results is discouraged" (Page 3)
Technical Brief: Tuberculosis, Gender and Human Rights (April 2017)	"Actions that can be taken to change policies and laws that undermine the uptake and effectiveness of TB programs [include] reforming intellectual property regulations and laws and regulatory frameworks for medicine registration. [...] A principal recipient of a Global Fund grant in Ukraine used the leverage of Global Fund support to negotiate a concessionary price with the manufacturer of the medicines and to push the government to agree to speed up registration and assume more of the treatment costs" (Page 9)
Technical Brief: HIV, Human Rights and Gender Equality (October 2019)	"There remain many policies and laws that impede access, undermine proven HIV health strategies and discriminate against key populations. [...] Some countries currently have regulations and policies involving mandatory testing, disclosure and treatment; registration of people who use drugs; user-fees; failure to take into account flexibilities in intellectual property law; and sterilization of HIV positive women" (Page 15)

In 2018, the Global Fund published several baseline assessments for scaling up programs to reduce human rights-related barriers to HIV and TB services. These assessments were conducted by external independent consultants and do not necessarily reflect the views of the Global Fund. Yet, they provide further rationale for the inclusion of activities to improve access to quality and affordable medicines in human rights programs supported by the Global Fund.

In **UKRAINE's** assessment, elements of the proposed comprehensive program include:

- Advocating for a law on the treatment and rehabilitation of people who inject drugs at the expense of the state budget through a system of free voluntary rehabilitation centers.
- Changing laws that regulate monopolies on medicines to improve economic affordability of medicines needed by key populations and PLHIV.
- Strengthening capacity key populations in budget advocacy skills is also noted. <sup>16</sup>

In **KYRGYSTAN's** baseline assessment, work on laws in relation to Intellectual property and generic medicines availability is captured as part of programs to monitor and reform laws, regulations and policies related to HIV. <sup>17</sup>

## WHAT ABOUT HEP C TREATMENT?

The Global Fund does not allocate HCV funding to countries. It only allocates funding for HIV, TB and malaria. However, the Global Fund supports HCV interventions in its grants, in accordance with its Policy on Co-infections and Co-morbidities. In April 2015, when the policy was adopted, an important decision was made to allow for HCV treatment to be included in Global Fund grants (Table 3).

**Table 3. Global Fund Policy on Funding Hepatitis C Treatment**

Global Fund Document	Relevant Text
Policy on Co-infections and Co-morbidities (April 2015) <sup>18</sup>	"The Board approved an interim measure for continued funding of Hepatitis C virus treatment until there is an outcome to broader discussions on the role of the Global fund with respect to funding treatment of co-infections and co-morbidities of HIV/AIDS, tuberculosis and malaria" (Page 1).

A number of countries are currently funding HCV treatment directly with their Global Fund grants, including Thailand, South Africa and Ukraine. In Georgia, the Global Fund grant supports linkage and referral activities to government-funded HCV treatment centers.

## NAVIGATING SENSITIVE POLITICS

Despite clear articulation in the Global Fund's formal policies on the intention to improve access to quality and affordable medicines, it is important to be aware that there are sensitivities on certain aspects. Four of the experts consulted for this toolkit said that IP activities were removed from Global Fund funding requests, either by the CCM or by the Global Fund Secretariat. These experts spanned the Asia-Pacific, Eastern Europe and Central Asia (EECA), Middle East and North Africa (MENA), and the Latin America and Caribbean (LAC) regions. Two more experts noted discussions at the Global Fund Board.



*"Price reduction and treatment optimization are the areas in the Global Fund grant. But from what I know, IP has been removed. Patent oppositions have been removed."*

Treatment activist working in RUSSIA, BELARUS, ARMENIA and KAZAKHSTAN



*"I had a meeting with the Fund Portfolio Manager once. I raised the issue of the price of ARVs and the need for the new ones. I asked them, 'what are you going to do about IP and patents'? They said Global Fund doesn't want to work on that."*

Treatment activist working in THAILAND



*"Due to Board level guidance, we are often limited in the type of work we can do around IP."*

GLOBAL FUND SECRETARIAT representative

Part of navigating these sensitive politics involves considering the type of activity – or the framing of that activity – so that it will be more likely to remain in the funding request and remain in the grant. Experts from the LAC region and the African region both mentioned cost-sharing with as a key strategy to get the necessary IP-related work done.



*"Cost-sharing seems a key strategy. Global Fund can fund the trainings and joining of actors, and maybe even the lawyer, but another donor funds the action for oppositions and compulsory license."*

Treatment activist in GUATEMALA



*"The [Global Fund] money is to engage and keep engaging the Central Drug Authority and the powers that be. It's really money for meetings. It's not money for Strategic litigation. That might be a step too far. We are engaging with Pro Bono lawyers to do the messier litigation stuff."*

Treatment activist in SOUTH AFRICA

Based on information in Global Fund policies, and advice from the experts consulted, Table 4 presents guidance on which activities to improve access to quality and affordable medicines are more likely to get included in Global Fund grants.

**Table 4. Likely and unlikely activities to be funded through Global Fund grants**

Activities the Global Fund is <b>MORE LIKELY</b> to fund	Activities the Global Fund is <b>LESS LIKELY</b> to fund
<b>Treatment literacy workshops</b>  These workshops can include information in IP literacy, procurement literacy, and analyses of legal and trade barriers to accessing medicines.	<b>IP workshops with civil society</b>  Experts suggest that these kinds of activities have been removed from Global Fund grants in the past.
<b>Strategic litigation and legal support</b>  This could include having a community-friendly lawyer on retainer to support initiatives that will remove human rights barriers to access for key populations. It could also include going through formal processes to challenge laws or policies that create such barriers.	<b>Submission of patent oppositions</b>  Though not strictly against Global Fund policy, experts suggest these activities are sometimes removed from Global Fund grants due to political sensitivities. It may be more strategic to use Global Fund resources to retain legal support or policy advisors, and find another partner to co-finance the rest of the process.



Activities the Global Fund is <b>MORE LIKELY</b> to fund	Activities the Global Fund is <b>LESS LIKELY</b> to fund
<p><b>Advocacy to reduce the price of medicines</b></p> <p>This may include funding for treatment activists to meetings with government officials, as well as advocacy for fast-tracked registration of new drugs (to end current monopolies).</p>	<p><b>Advocacy to push for compulsory licenses</b></p> <p>As above, this is not strictly against Global Fund policy but experts suggest these activities are sometimes removed. Seeing other co-financing for this activity may be a strategic approach.</p>
<p><b>Assessments and reviews related to human rights, gender, sustainability and transition</b></p> <p>This includes legal environment assessments, assessments of human rights-related barriers to access, the gender assessment tool, transition readiness assessments and sustainability reviews. IP and A2M analyses can form part of these assessments and reviews.</p>	<p><b>IP landscape assessments</b></p> <p>Though not strictly against Global Fund policy, experts suggest these activities are sometimes removed from Global Fund grants due to political sensitivities. It might be more strategic to integrate this topic into the other broader types of assessments listed here.</p>
<p><b>Advocacy to increase domestic health funding and monitor budget execution</b></p> <p>This could include pushing governments to dedicate a greater proportion of their budget to health, lobbying for new or specific budget lines for HIV, TB or HCV, tracking domestic health financing, or monitoring domestic health budget execution.</p>	<p><b>Advocacy for increased pledges to the Global Fund, or advocacy for changes to the Global Fund's eligibility policy</b></p> <p>This kind of advocacy would be a conflict of interest, if funded through Global Fund resources. However, other funding partners do fund this kind of work.</p>

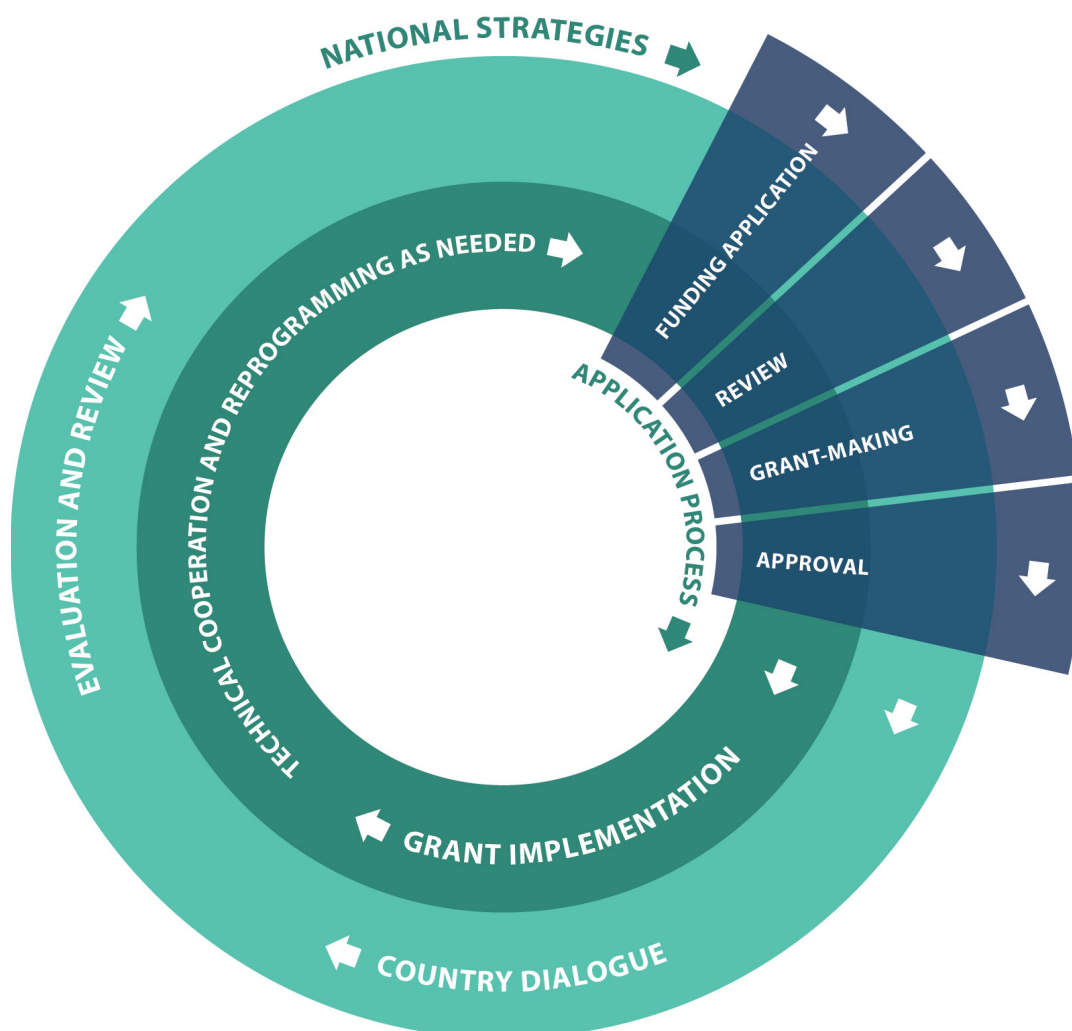


**COMMUNITY TIP:** Find allies within the Global Fund who support inclusion of activities to improve access to quality and affordable medicines in Global Fund grants. These may include people within the Community, Rights and Gender Department, the Sustainability, Transition and Co-financing Unit, or members of your Country Team. Experts say having these allies is helpful.

## → PART 4: THE FUNDING MODEL

### STEPS IN THE PROCESS

The Global Fund funding model has six main steps in the process:



**Figure 1. The Global Fund Funding Model**

- (1) National strategies (6 months)
- (2) Funding requests (2-3 months)
- (3) Review (2 months)
- (4) Grant-making (8 months)
- (5) Approval (1 month)
- (6) Implementation (3 years)

These steps occur in 3-year cycles. The next funding cycle is 2020-2022. Understanding the advocacy entry points in the process is key to engaging effectively and for getting activities to improve access to quality and affordable medicines successfully included in Global Fund grants (Figure 2).

## KEY DATES AND TIMELINES

For the 2020-2022 funding cycle, most countries will review their national strategic plans (NSPs) in 2019 and submit funding requests in one of the first three windows of 2020. In the last funding cycle, 159 out of 225 funding requests (more than 70%) were submitted in the first three application windows. Table 4 shows the submission and review dates for the first three application windows.

**Table 4. Submission and review dates for windows 1-3 of 2020-2022 funding cycle**

Window	Submission Date	Technical Review Panel (TRP) Review
1	23 March 2020	27 April – 2 May 2020
2	25 May 2020	29 June – 5 July 2020
3	31 August 2020	5-11 October 2020



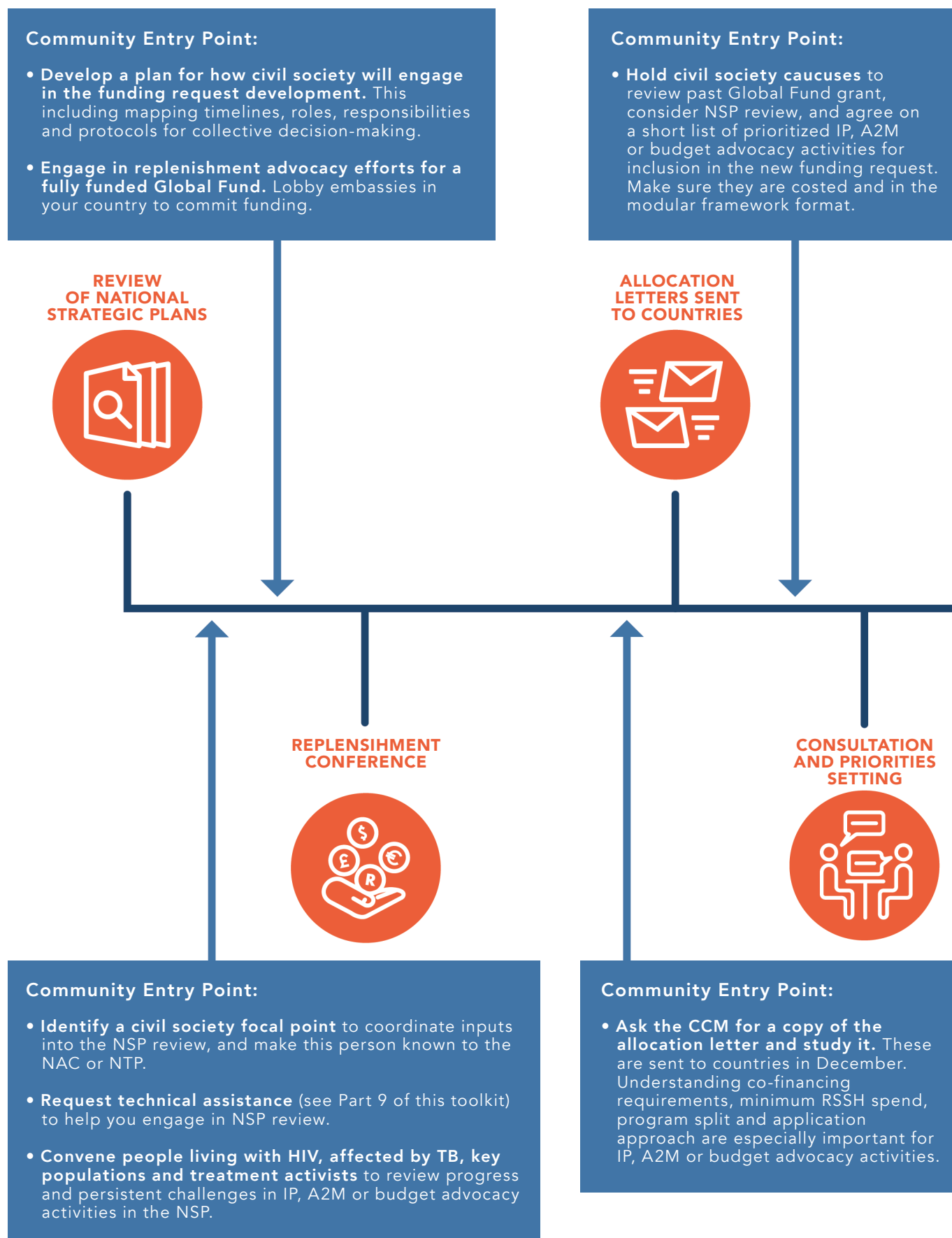
**COMMUNITY TIP:** Offer to brief your Fund Portfolio Manager and/or other members of your Global Fund Country Team on the IP, A2M and health budget advocacy activities in the funding request. The Country Team has to present the funding request to the TRP and convince them to approve it. Properly briefing them on the rationale for your activities may help.

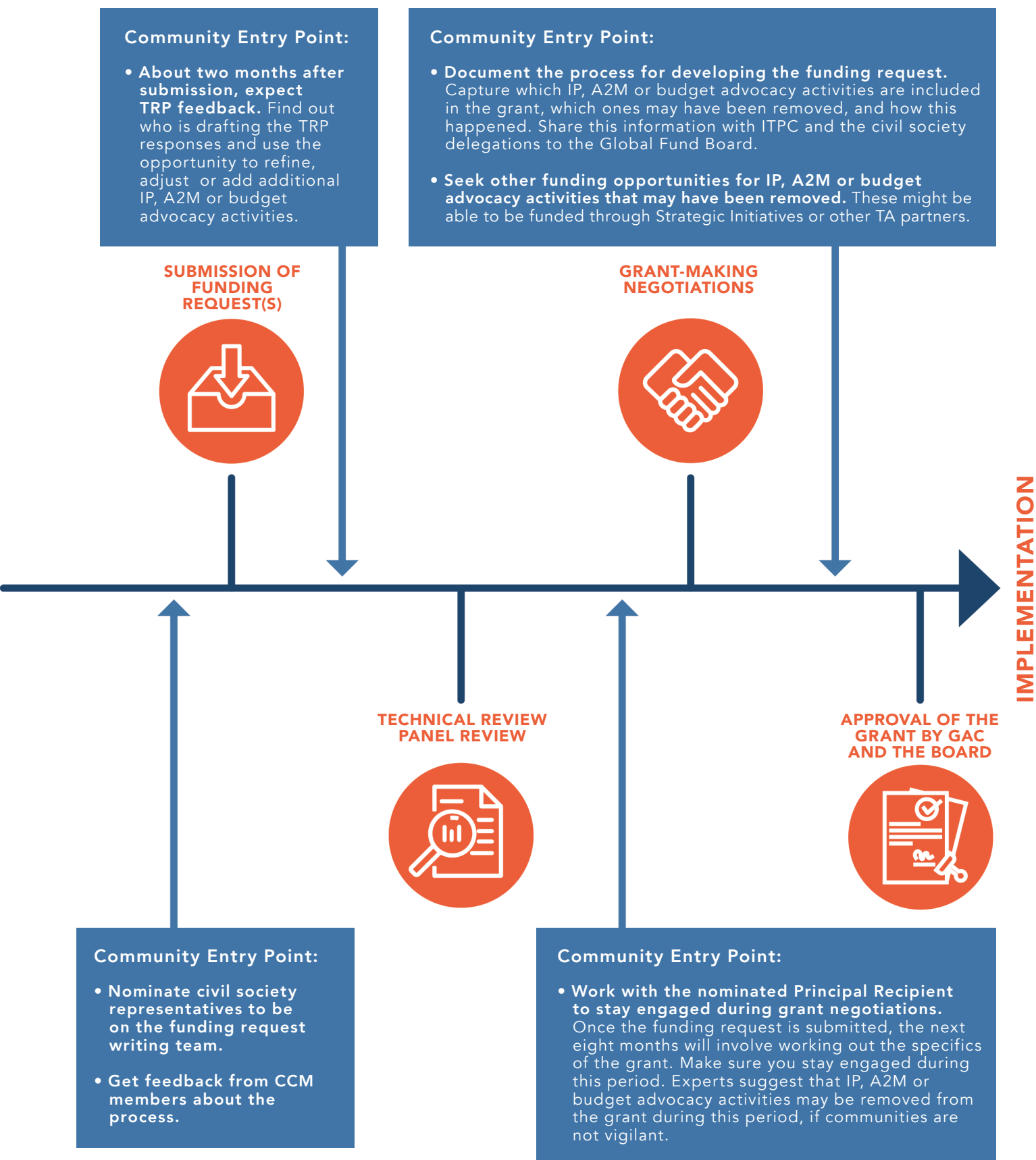


Effective advocacy and processes can increase access and get essential treatment into people's hands.

© Gemma Taylor/ Make Medicines Affordable

**Figure 2. Key Entry Points in the Funding Model for Including Activities to Improve Access to Quality and Affordable Medicines in Global Fund Grants**





## PART 5: GLOBAL FUND “SPEAK”

Understanding the language of the Global Fund is important. It is useful to frame activities so that they align with Global Fund policies, guidelines and objectives, as well as global normative guidance from technical partners. Further, given the sensitivities already mentioned in Part 2 of this toolkit, certain words or phrases may be more strategic than others.



*“We need sample language to use that will enable IP advocacy without sending red flags. It will help to know the language that is likely to get flagged vs. language that may get through.”*

Treatment activist in GUATEMALA

Table 5 provides examples of how activists can phrase activities to improve access to quality and affordable medicines in a way that may be more acceptable for the Global Fund. It is important to note that this guidance is based the experience of ITPC and its partners. It is not guidance from the Global Fund itself.

**Table 5. Strategic language to use in Global Fund funding requests and transition work plans for describing activities that improve access to quality and affordable medicines**

DO SAY	DON'T SAY
Do advocacy with government to strengthen health products management systems and improve access to medicines	Do IP advocacy
Update the regulatory legal framework and policies and optimize the registration process	End drug supplier monopolies
Make health products management systems more sustainable in the context of transition	Bring the prices of medicines down
Obtain quality inputs at the lowest possible cost through a value for money approach	
Pursue strategic litigation opportunities to remove human rights-related barriers to accessing medicines	File patent oppositions
Advocacy to prevent low quality patents Improve laws	Change/reform laws
Retain community-friendly legal and paralegal support to ensure that people most affected by HIV and TB – including key populations – are able to effectively advocate for their right to health.	Sue the government



DO SAY	DON'T SAY
Advocacy and mobilization for law and policy reform to increase access to services	Advocacy against TRIPS+ measures
Identify procurement efficiencies to ensure the lowest possible price for products of assured quality	Ensure the availability of generic medicines
Conduct a legal environment assessment with a specific focus on human rights-related barriers to accessing essential medicines	Review IP laws



Ensuring the lowest possible price for optimal treatment will improve people’s treatment regimens and lives.  
 © Gemma Taylor/ Make Medicines Affordable

## PART 6: THE APPLICATION FORMAT

### CATEGORIZING ACTIVITIES IN THE MODULAR FRAMEWORK

The modular framework is the Global Fund's way of organizing programmatic and financial information for each grant throughout its life cycle, from the initial funding request to grant-making and implementation. The Modular Framework must be used by all applicants during funding request development for the 2020-2022 Global Fund funding cycle.

Understanding the modular framework is important for categorizing requested activities and their associated budgets and targets. CCMs, writing teams, the Global Fund Secretariat and the TRP may be more receptive to funding requests that are categorized in this way.



**COMMUNITY TIP:** When submitting activities to improve access to quality and affordable medicines to the CCM or the writing team for inclusion in Global Fund funding requests, create a table that is structured in line with the module framework. Make it clear which module and intervention your activities fall under. This will make it more likely for them to be included.

**Table 6. Where activities to improve access to quality and affordable medicines fit into the Global Fund's modular framework**

Module (preset)	Intervention (preset)	Scope and description of intervention package (specific activities to be determined by countries)
The HIV Modular Framework		
Reducing human rights-related barriers to HIV/TB services	HIV and HIV/TB-related legal services	<ul style="list-style-type: none"> <li>• Legal information, referrals, advice and representation related to HIV and HIV/TB, including through peer paralegal community systems</li> <li>• Strategic litigation</li> </ul>
	Improving laws, regulations and policies relating to HIV and HIV/TB	<ul style="list-style-type: none"> <li>• Legal Environment Assessments, and community-based monitoring of laws and their implementation in terms of their impact on health and access to services</li> <li>• Advocacy and mobilization for law and policy reform to increase access to services</li> </ul>
	Community mobilization and advocacy	<ul style="list-style-type: none"> <li>• Patient group mobilization and building capacity/supporting community-led advocacy efforts</li> </ul>
Treatment, care and support	Differentiated ART service delivery and HIV care	<ul style="list-style-type: none"> <li>• Development of tools such as treatment literacy and preparedness</li> </ul>

Module (preset)	Intervention (preset)	Scope and description of intervention package (specific activities to be determined by countries)
<b>The TB Modular Framework</b>		
TB care and prevention	Engaging all care providers	<ul style="list-style-type: none"> <li>• Incentives and enablers to motivate care providers to deliver quality TB prevention and care services</li> </ul>
MDR-TB	Treatment	<ul style="list-style-type: none"> <li>• Introduction and scale up of all-oral regimens (including all-oral shorter regimens under operational research) for DR-TB patients that include new and repurposed drugs as per the new WHO guidelines</li> </ul>
Removing human rights and gender related barriers to TB services	Reform of laws and policies	<ul style="list-style-type: none"> <li>• Engagement with Parliamentarians, Ministry of Justice, Interior, Corrections, religious and community leaders, among others, for advocacy and sensitization</li> <li>• Legal audit, Legal Environment Assessments</li> <li>• Monitoring of laws and policies, including the compliance</li> </ul>
	Community mobilization and advocacy	<ul style="list-style-type: none"> <li>• Patient group mobilization and building capacity/ supporting community-led advocacy efforts</li> </ul>
<b>The Resilient and Sustainable Systems for Health (RSSH) Modular Framework</b>		
RSSH: Health products management systems	Policy, strategy, governance	<ul style="list-style-type: none"> <li>• Development or update of a national medicines policy</li> <li>• Development or update of a national strategy for procurement and supply chain management/logistics plan/implementation plan</li> <li>• Update of the essential medicines lists, national drug formularies and standard treatment guidelines</li> </ul>
	Procurement capacity	<ul style="list-style-type: none"> <li>• Assessment of procurement capacity</li> <li>• Capacity building for improved supply/demand analysis, widening value for money procurement options, procurement performance monitoring, etc.</li> </ul>
	Regulatory/ quality assurance support	<ul style="list-style-type: none"> <li>• Update of the regulatory legal framework and policies</li> <li>• Optimizing registration process for more rapid uptake of new technologies</li> </ul>
RSSH: Health Management Information Systems and M&E	Surveys	<ul style="list-style-type: none"> <li>• Community-led surveys</li> <li>• Health and morbidity surveys to assess out-of-pocket expenditures</li> <li>• Qualitative surveys on facilitators and barriers to access to services, specific needs of different key populations</li> </ul>

Module (preset)	Intervention (preset)	Scope and description of intervention package (specific activities to be determined by countries)
RSSH: Community systems strengthening	Community-based monitoring	<ul style="list-style-type: none"> <li>• Development, support and strengthening of community-based mechanisms that monitor:               <ul style="list-style-type: none"> <li>o Availability, accessibility, acceptability and quality of services (e.g. observatories, alert systems, scorecards)</li> <li>o Health policy, budget and resource tracking, and monitoring of health financing allocation decisions.</li> </ul> </li> <li>• Community-based monitoring of barriers to accessing services for purposes advocacy to improve programs and policies.</li> </ul>
	Community-led advocacy and research	<ul style="list-style-type: none"> <li>• Qualitative, quantitative and operational community-led research and the production, publication and dissemination of reports and communication materials</li> <li>• Community-led mapping of legal, policy and other barriers that hinder/limit community responses (including barriers that impede registration, funding of community organizations)</li> <li>• Capacity building to develop and implement advocacy campaigns for domestic resource mobilization for the three diseases and UHC</li> <li>• Advocacy activities, including conducting situational analysis, engagement and representation in policy processes, decision-making and accountability mechanisms and processes, and in the development of local, regional and national strategies and plans</li> </ul>



**COMMUNITY TIP:** Once national priorities are identified through country dialogue and in National Strategic Plans, it may be helpful to refer to the Modular Framework to help you use “Global Fund Speak” when drafting the narrative for your activities.



**COMMUNITY TIP:** In addition to the main allocation, catalytic funding may be another strategic place to put activities that improve access to quality and affordable medicines. This might include human rights matching funds (for 20 countries<sup>19</sup>), or multi-country grants.<sup>20</sup>

Once you have identified which modules, interventions, and activities you want to include in the Global Fund grant, it can be helpful to submit your narrative to CCMs and writing teams using the Global Fund application format. Figure 3 provides an example of how to do this.

**Figure 3. Sample text in funding request format to submit to CCMs or writing teams**



<b>Module (#)</b>	Reducing human rights-related barriers to HIV/TB services
<b>Intervention(s) &amp; Key Activities</b>	<p><b>Intervention:</b> Improving laws, regulations and policies relating to HIV and HIV/TB</p> <p><b>Activities:</b> [Country name] requests funding to support community-based monitoring of procurement laws, policies and processes for [name of medicines and/or commodities], and their implementation in terms of their impact on health and access to services. This will include a baseline landscape assessment of the barriers to accessing affordable medicines, followed by the publication of quarterly policy watch briefs which track their impact on communities and opportunities for change. Funding will also support advocacy and mobilization for law and policy reform to increase access to [type of health of service], using the materials produced to inform quarterly multi-stakeholder roundtables among affected communities, the [name of ministry of health], [name of the national regulatory authority], [name of national AIDS council] and [names of other key stakeholders, as relevant]. These activities will be led by [name of the national network of people living with HIV], in partnership with key populations and treatment access networks.</p>
<b>Priority Population(s)</b>	People living with HIV and [list other HIV key populations for your context, as relevant]; people affected by TB
<b>Barriers and Inequities</b>	The price of [name of drug or commodity] is prohibitively expensive in [name of country]. While it is covered by most private insurance companies, it is not part of the basic health service package provided by the state. This creates health inequities, where people with private health insurance have access to better quality care than people who cannot afford it.
<b>Rationale</b>	In order for [country name] to move towards universal health coverage, it is imperative that the price of [name of drug or commodity] be reduced or for other procurement alternatives or efficiencies to be identified.
<b>Expected Outcome</b>	A [%] price reduction in the cost of [name of drug or commodity] An additional [#] of people accessing [type of health of service]
<b>Expected Investment</b>	<p>[Estimated cost of activities = \$100,000-\$150,000 over 3 years]</p> <p>If this funding is granted, [name of country] will be able to unlock an estimated [dollar amount] in additional value of investment from [name of law firm], which has committed to support these advocacy activities with pro bono legal advice on patent and procurement law, drug registration processes, and options for strategic litigation.</p>

## COSTING AND BUDGETING

When submitting activities to CCMs or writing teams for inclusion in Global Fund funding requests, it is advisable to ensure they are properly costed. This can be an estimated cost at the time of funding request submission, with more detailed costing done during grant-making. As with activity narratives, the budget should also be submitted in the format of the modular framework, indicating the module, intervention, priority population (if applicable) and specific activity, for each budget line.



**COMMUNITY TIP:** Make sure the activities to improve access to quality and affordable medicines that you submit to CCMs or writing teams are either already costed, ideally using the Global Fund budget template, or have sufficient detail so the writing team can cost them for you. Sometimes, community priorities are not included in funding requests because they are too vague.

It may be helpful to ask the CCM or writing team for an indicative budget for your activities. They may give you a rounded estimate of the funding available for specific modules, such as community systems strengthening, or for reducing human rights-related barriers to HIV/TB services. It will improve the likelihood that your activities will be included if you stick within the budget ceiling indicated.

However, be sure to also include at least 30% on top of the indicative budget as a prioritized above allocation request (PAAR). This should preferably focus on fewer, larger, high impact investments. While these activities will not be included in the grant at first, they will be reviewed by the TRP and will sit in the register or unfunded quality demand (UQD). These activities can be funded at a later date, through Global Fund portfolio optimization, private sector investments, or Debt2Health agreements. In the last funding cycle, almost US\$1 billion in interventions from the UQD register were funded through savings and efficiencies identified during grant negotiation and grant implementation.



**COMMUNITY TIP:** Clearly mark all your activities that you submit to the CCM or the writing team in order of priority (i.e. "Module #1", "Module #2"). This will increase the likelihood that some of your activities get included, even if not all of them can. The prioritization should be clearly marked for all activities, both within and above allocation. If your activities cannot fit in the allocation amount, make sure they are included in the Prioritized Above Allocation Request (PAAR). In the 2017-2019 funding cycle, 30% of PAAR activities were ultimately funded, either through grant savings or additional funds from the Global Fund's Portfolio Optimization funding stream.

## INDICATORS FOR THE PERFORMANCE FRAMEWORK

It is also advisable to submit specific indicators, or work plan tracking measures (for RSSH modules) that can go in the performance framework. Table 7 has some example core Global Fund indicators to include in the performance framework to track progress on activities that improve access to quality and affordable medicines.



**Table 7. Core indicators to measure activities that improve access to quality and affordable medicines**

Module	Indicator code	Global Fund core Indicator
RSSH: Health products management systems	PSM-4	Percentage of health facilities with tracer medicines for the three diseases available on the day of the visit or day of reporting
RSSH: Community systems strengthening	CSS-1	Percentage of community-based monitoring reports presented to relevant oversight mechanisms
	CSS-2	Number of community-based organizations that received a pre-defined package of training

In addition to the core Global Fund indicators listed in the Modular Framework Handbook, countries may develop their own custom indicators and include them in the performance framework. For activities that improve access to quality and affordable medicines, custom indicators may be more appropriate.

Example custom indicators to measure activities that improve access to quality and affordable medicines include:

- ➡ **HIV O – other:** # of instances where there is evidence that civil society organizations and key population networks have influenced laws, policies or practices that present barriers to delivery of HIV treatment
- ➡ **HCV O – other:** # of instances where there is evidence that civil society organizations and key population networks have influenced laws, policies or practices that present barriers to delivery of HCV treatment
- ➡ **TB O – other:** # of instances where there is evidence that civil society organizations and key population networks have influenced laws, policies or practices that present barriers to delivery of TB treatment
- ➡ **HIV O – other:** # instances where civil society has meaningfully participated in policy and budget decisions relating to HIV
- ➡ **HCV O – other:** # instances where civil society has meaningfully participated in policy and budget decisions relating to HCV
- ➡ **TB O – other:** # instances where civil society has meaningfully participated in policy and budget decisions relating to TB
- ➡ **HIV O – other:** Amount and % of domestic HIV funding budgeted for key population programming
- ➡ **TB O – other:** Amount and % of domestic TB funding budgeted for key population programming
- ➡ **HIV O – other:** # of local civil society organizations receiving funding through domestic mechanisms (government or private sector) in the past 12 months
- ➡ **RSSH Work plan tracking measure:** Level of reduction of HIV medicines prices
- ➡ **RSSH Work plan tracking measure:** Level of reduction of HCV medicines prices
- ➡ **RSSH Work plan tracking measure:** Level of reduction of TB medicines prices

## PART 7: REAL-WORLD EXAMPLES

Experts consulted for this toolkit overwhelmingly emphasized the usefulness of real-world examples. The following examples come from the most recent funding requests submitted by countries to the Global Fund. They include many activities that improve access to quality and affordable medicines.



**COMMUNITY TIP:** Use these real-world examples from the last round of Global Fund funding requests to get ideas for what the 2020-2022 funding cycle. Adapt or replicate these approaches, techniques, or language in your country's next Global Fund funding request. Rely on these examples in negotiations with the CCM or with the Global Fund, to justify their inclusion in your country's request.

### ACTIVITIES IN PAST FUNDING REQUESTS



**COUNTRY EXAMPLE:** In **SOUTH AFRICA**, the price of opioid substitution therapy (OST) for PWID is up to 30 times higher than in Georgia and the Ukraine. The reason stems from monopoly pricing; there is only one company registered under South African Health Products Regulatory Authority (SAPHRA). In South Africa's current Global Fund HIV grant, which began implementation in April 2019, R816,000 (about \$55,000) is included for advocacy activities to reduce the price of OST. This will support the time of leading technical experts with the South African Network of People who use Drugs (SANPUD). An additional R89,000 (about \$5,800) is included for quarterly meetings between SANPUD, the South African National AIDS Council (SANAC) and the Central Drug Authority (CDA). This is to advocate for OST to be registered on the essential drug list for long term drug dependence treatment. SANPUD has leveraged this funding from Global Fund to attract other funding from the Open Society Foundations (OSF) (for core network support) and pro bono services from a large corporate law firm (for strategic litigation, challenging the price of OST in the constitutional court under the right to health).



**COUNTRY EXAMPLE:** In **EL SALVADOR**'s most recent HIV funding request to the Global Fund, submitted in April 2018, the country describes several planned actions to improve the sustainability of Global Fund financed programs. One such action is a TRIPS Flexibility Strategy. The funding request notes that "the use of flexibilities is important for the country because, in the case of Ritonavir-Lopinavir [...] a potential patent right uses up more than 50% of the budget for purchasing ARVs." The funding request states that the USAID-funded Program for Strengthening the Central American Response to HIV/AIDS (PASCA) – a regional HIV/AIDS program operating in Guatemala, El Salvador, Honduras, Nicaragua, and Panama – will lead the work on the country's TRIPS Flexibility Strategy, to bring about an amendment to the law.<sup>21</sup>



**COUNTRY EXAMPLE:** In **BELARUS** there are 19 registered ARV products, 16 of which are distributed by suppliers with drug patents. There are also 13 ARV products with no valid patents, but only 3 are registered. There are several provisions in the law which allow suppliers of unregistered drugs to bid on procurement procedures, or to apply to the MoH for a permit for a single entry of the drug. In the country's 2015 HIV funding request to the Global Fund, 13% of the budget was for enabling environment activities, including building the procurement and supply chain management capacities of the new PR through training, on-site support, procedure development and exchange visits. The aim was to enable rapid, quality and value-for-money procurement of commodities and drugs for the program, including navigating the legal context described.<sup>22</sup>



**COUNTRY EXAMPLE:** In **KYRGYZSTAN's** most recent TB/HIV funding request to the Global Fund, submitted in March 2017, a plan to transfer the PR function from UNDP to the MoH is articulated. This plan is based on a previous request of the Global Fund's TRP. The funding request states that "It is planned to work further on improving capacities of the MoH to take over procurement of TB and HIV medicines using international procurement agencies (e.g. addressing homologation for high-quality generics, updating vital and essential drugs lists, set-up storage and distribution systems etc)."<sup>23</sup>



**COUNTRY EXAMPLE:** In **EL SALVADOR**, the MoH has faced difficulties as the PR of the Global Fund HIV grant, particularly with delays delivering commodities and medicines. A USAID-funded assessment found these challenges were linked to institutional rules and regulations of the procurement law (LACAP) and scarce human resources. The country is addressing these specific gaps in the new grant.<sup>24</sup>



**COUNTRY EXAMPLE:** In **GUATEMALA's** most recent HIV funding request, submitted in February 2018, the following activity was included: "Presenting a bill for the reform of the intellectual property law, to fully reflect all the flexibility currently afforded to Guatemala through international legislation (including "TRIPS-plus" CAFTA-DR trade agreement ), guaranteeing low-cost generic drugs." It is linked to other parts of the request. It mentions "failure to discuss alternatives included in patent agreements" as a key implementation risk (Section 3.2), mentions "implementation of an advocacy process through CSOs, geared toward authorization of the compulsory licensing of generic drugs" as a planned action to enable greater efficiency and effectiveness of health spending (Section 4.1), and mentions that the sustainability of the program will be ensured, provided that the approval of a bill for the reform of the IP law is achieved (Section 4.2).<sup>25</sup>



**COUNTRY EXAMPLE:** In **UKRAINE's** most recent TB/HIV funding request to the Global Fund, submitted in May 2017, there is a custom indicator in the Performance Framework (under work plan tracking measures) on the "Level of reduction of ARV medicines prices for MoH Ukraine". In the comments, it states that "this custom indicator is related to advocacy, regulatory and legal activities aimed at 1) overcoming patent monopolies on medicines; 2) reduction of prices by increasing competition in the market, including through generic substitution; 3) support of practical application by the Ministry of Health of Ukraine, Ukrainian Public Health Center and other authorized bodies, as well as non-governmental organizations of legal, procedural and regulatory mechanisms to ensure a reduction in prices for medicines. Price reduction for procured pharmaceuticals is one of the cornerstones in increasing coverage of treatment."



**COUNTRY EXAMPLE:** In **INDIA's** most recent TB funding request to the Global Fund, submitted in May 2017, US \$1.59m is included in the prioritized above allocation request for social marketing programs in five urban cities to ensure patients can access daily fixed-dose combination (FDC) TB drugs at an affordable cost from private retailers. The activity includes creating an aspirational brand to be owned by the Revised National TB Control Program (RNTCP), promotion, marketing, provision, and incentives for distributors and pharmacies to cover their cost of stocking, distributing and dispensing the FDCs.<sup>26</sup>



**COUNTRY EXAMPLE:** In **THAILAND**, a locally manufactured generic tenofovir-emtricitabine combination (TenoEm) is available and affordable at about \$20 for 30 tablets. However, the National Health Security Office (NHSO) does not currently reimburse for pre-exposure prophylaxis (PrEP), and Thai drug regulatory authorities have not approved the labelling of the generic combination for HIV prevention purposes. The country's most recent TB/HIV funding request to the Global Fund, submitted in August 2017, includes activities "to generate demand for fee-for-service PrEP, which is widely available but is underutilized in health settings across Thailand." It also includes activities to "review and documentation of the work of Thai and international groups that may be presented to NHSO as they consider incorporating PrEP into the universal health coverage scheme."<sup>27</sup>



**COUNTRY EXAMPLE:** In **KAZAKHSTAN's** most recent HIV funding request to the Global Fund, submitted in May 2017, funding was requested to support community-led budget advocacy for HIV prevention, care and support services to key populations. It included a series of advocacy meetings, conducted through NGO Aman-Saulyk at central and local level to increase awareness about social contracting and financial commitment of public authorities such as the MoH, Akimats and AIDS Centers. In parallel, the Kazakh Union of PLHIV would conduct communication campaigns with partner NGO, to increase awareness about the role of communities in HIV services for key populations, promote social contracting mechanisms, and advocate for budget increases.<sup>28</sup>



**COUNTRY EXAMPLE:** In **UZBEKISTAN**'s most recent HIV funding request to the Global Fund, submitted in March 2017, a key outcome of the proposed program was to have social contracting for HIV prevention and key populations through civil society organizations. To achieve this, funding was requested continue conduct budget advocacy activities at national and regional levels. In order to ensure broad involvement of communities, terms of reference would favor applications forming consortiums of national and local organizations and community groups.<sup>29</sup>



**COUNTRY EXAMPLE:** In **THAILAND**, the national network of PLHIV already assist clients in making linkages to informal "buyers' clubs"<sup>30</sup> to import direct-acting antivirals (DAA) to provide affordable access to HCV cure treatments for PWID. In the country's August 2017 TB/HIV funding request to the Global Fund, funding was requested to support HCV screening among PWID, referring those with reactive results to community sites supporting buyers' clubs. The request says that "affordable generic DAAs will be imported with grant resources from countries that do not currently face licensing restrictions to fill a gap in the need for lifesaving HCV treatment and optimize service-delivery models as Thailand continues to pursue critical licensing negotiations." In the PAAR, \$48,984.27 is requested for a Training of Trainers to build communication networks on DAA, including patents, drug registrations and access. The aim is to prepare outreach workers, field staff, and buyers' club members for DAA advocacy.



**REGIONAL EXAMPLE:** In the **EECA** multi-country HIV funding request, submitted in April 2017, funding was requested to challenge patent barriers for priority ARVs by filing patent oppositions/invalidation lawsuits; support efforts on the promotion of patent law reform aimed at TRIPS-flexibilities implementation and mitigating TRIPS-plus mechanisms; starting a dialogue on voluntary and compulsory licensing with the government or patent holder; develop and discuss the removal of technical barriers to the competition of multiple generic medicines suppliers, and uptake of generic HIV, anti-TB, hepatitis medicines; and a dialogue between CSOs, health officials and manufacturers of branded and generic ARV drugs on price reduction issues and in coordination with the Medicines Patent Pool on attracting new producers of generic and cost-efficient branded medicines to the market.[1]



**COMMUNITY TIP:** When civil society organizations and governments agree on an activity that improves access to quality and affordable medicines, it has a better chance of getting include in a Global Fund grant. CSOs are encouraged to reference their NSP or a national priority document, and emphasize that the activity is a national priority that is collectively endorsed by civil society, affected communities, and the Government.

[1] It is important to note that civil society organizations were not ultimately successful getting many of these activities funded. Experts involved in the process suspect that not having government backing (it was a civil society-led funding request) was a factor.

## LESSONS LEARNED



**LESSON LEARNED:** A key lesson learned in **UKRAINE** during the 2014-2016 funding cycle was about the importance of implementing activities that are contained in the country's sustainability and transition plan. The country's most recent funding request, which was submitted in May 2017, notes that based on this lesson "more legislation changes and activities are planned for implementing the anti-corruption legislation in the pharmaceutical sphere, patent and intellectual property demands."<sup>31</sup> Advocates should ensure that IP and A2M activities are including in such plans, and that government endorses the plans. This may increase the likelihood that these activities can then be funded through Global Fund grants.



**LESSON LEARNED:** In 2017, the TRP asked **SOUTH AFRICA**, to provide clarification on the expansion of the National Department of Health's 'Central Chronic Medicine Dispensing and Distribution' program, including a description of the geographic roll out, and how the Visibility and Analytics Network will address last mile stockouts and guarantee access to medicines in all areas across the country. Learning from South Africa, countries should ensure that they include information about location- or population-based inequities with respect to access to medicines in their funding request, as well as strategies for how these will be addressed.<sup>32</sup>



**LESSON LEARNED:** Following the country examples of **SOUTH AFRICA** and **EL SALVADOR**, it is helpful to bring other partners on board to co-finance IP-related advocacy work. This may be particularly useful for strategic litigation, which may be harder to include in Global Fund grants than other advocacy activities. If you can show that the inclusion of certain IP-related activities in the Global Fund request will "un-lock" or leverage additional funding from another partner, this will make it more likely that they are funded by the Global Fund.



**LESSON LEARNED:** Following the country examples of **BELARUS**, **KYRGYZSTAN** and **EL SALVADOR**, include capacity strengthening activities in Global Fund funding requests to ensure that Principal Recipients – especially new(er) ones – are able to understand and exploit existing legal frameworks to optimize procurement of affordable medicines. This can include training on the legal frameworks and their various provisions, mentoring from previous or more experienced Principal Recipients, or exchange visits to other countries with similar legal and policy contexts.



**LESSON LEARNED:** Following the country examples of **KAZAKHSTAN** and **UZBEKISTAN**, ensure that communities of key populations, people living with HIV and people affected by TB and HCV are the ones to receive budget advocacy funding and lead those activities. Evidence suggests that involving communities most affected by HIV, TB and HCV – particularly in leadership roles – can lead to better outcomes in health budget advocacy.<sup>33</sup>





**LESSON LEARNED:** Following the country examples of **GUATEMALA** and **UKRAINE** include IP-related information in all sections and attachments of the funding request, including Section 1 (Country Context), Section 2 (Funding Request), Section 3 (Operationalization) and Section 4 (Sustainability), the Budget, and the Performance Framework. Some countries include this information in the country context section, but do not include specific activities with clear budget lines and targets.



**LESSON LEARNED:** In 2017, the TRP noted that **NIGERIA's** malaria funding request included a large request for artemisinin-based combination therapies (ACTs) subsidy for the private sector with no apparent aggressive plan to end this expense initiative which currently covers 85% of the price of ACTs. The TRP said that an accelerated and more aggressive plan for phasing out the ACT co-payment should be provided to the Global Fund, and that it should include use of Global Fund recommended suppliers even for government procurements. Based on this lesson, while private sector drug suppliers and fee-for-service access is sometimes strategic (recall country examples on PrEP in **THAILAND** and TB FDCs in **INDIA**), a plan to move towards universal health coverage for essential medicines should be part of funding requests.

## SUCCESS STORIES



**SUCCESS STORY:** In **MACEDONIA**, the Global Fund provided extensive support to ensure there is no disruption of services after the transition. Budget advocacy for CSOs, and Capacity building for CSOs to access public funding, has resulted in \$1 million annually in domestic funding of HIV prevention services.<sup>34</sup>



**SUCCESS STORY:** In **SOUTH AFRICA**, in October 2018, the Global Fund (and other partners) supported a high-level round table event on HIV and HCV. The event convened 28 experts from the National Department of Health (NDOH), United Nations Office on Drugs and Crime (UNODC), SAPHRA, implementing partners and community members. The meeting focused on epidemic updates, review of the national strategy, and discussions of political actions to reduce the price of Hep C treatment. At the meeting, the NDOH committed to include Hep C screening in the conditional HIV grants to provinces, and implementing partners committed to engage with the pharmaceutical industry to fund a Hep C demonstration project for PWID.<sup>35</sup>



**SUCCESS STORY:** In **KAZAKHSTAN**, access to generic sofosbuvir has been achieved, despite the country being outside the license. CSOs were a driving force, raising awareness among multiple stakeholders on the striking difference between the price of the originator and the price of the generics. This helped create greater demand for access to generics. This drive from CSOs helped decision-makers have a strong argument to start building other dialogues with patent holders and other stakeholders in the complex legal environment. This built the foundation for the inclusion in the license which will be announced soon. It also built the foundation for a government-supported program to eliminate HCV.<sup>36</sup>

## PART 8: CONVINCING THE CCM

The CCM is the body that is responsible for developing and submitting funding requests to the Global fund. Getting activities that improve access to quality and affordable medicines into the funding request requires convincing the CCM.

### STRATEGIES TO CONVINCE THE CCM

Strategies to convince the CCM to include your activities that improve access to quality and affordable medicines in Global Fund funding requests might include:

- Presenting analysis of the potential cost savings and increases in treatment coverage from accessing more affordable medicines
- Sharing examples of activities that improve access to quality and affordable medicines which were included in other countries' funding requests (recall Part 7 of this toolkit)
- Identifying civil society allies on the CCM and holding pre-meetings to strategize on how to get activities that improve access to quality and affordable medicines included in the funding request
- Forming alliances on the CCM, where multiple members agree to push for activities that improve access to quality and affordable medicines and to vote in favor of their inclusion
- Writing letters to the CCM, the Global Fund and/or the TRP to raise awareness of the importance of including activities that improve access to quality and affordable medicines in the funding request
- Lobbying civil society CCM members not to sign or endorse the funding request unless it includes activities that improve access to quality and affordable medicines
- Being persistent, and repeating the message during every opportunity

During negotiations at CCM level, the following arguments may be helpful for community activists:



*"Investing in activities that increase access to quality and affordable medicines is a cost-effective approach. In one country, they found that accessing a generic substitute would allow them to close the entire treatment gap. We need to include these activities in the grant in order to achieve the 90-90-90 targets"*



*"Investing in activities that increase access to quality and affordable medicines will enable our country to be more innovative and efficient, helping us meet the WHO recommendations more rapidly"*



*"Investing in activities that increase access to quality and affordable medicines is the only way our country will be able to keep the pace and accelerate the response given constrained global funding."*



*"Investing in activities that increase access to quality and affordable medicines will enable more people to receive efficient, life-saving treatment. Health is a human right and the Global Fund is very focused on human rights. They may reject our proposal if we do not address barriers and inequities"*



**COMMUNITY TIP:** Do an exercise to find out what your treatment guidelines say and compare them to the WHO guidelines. Next, find out what your country is paying for certain medicines and comparison to find out what other countries are paying for the same drug. Tools you can use include:

- The Global Price Reporting Mechanism for HIV, TB and malaria<sup>37</sup>
- The Medicines Patents and Licenses Database<sup>38</sup>

Ask to present your findings to the CCM, or prepare talking points for civil society CCM members. Use the rationale of the potential savings to push for inclusion of activities that increase access to quality and affordable medicines in the Global Fund grant.



*"It will be extremely hard to get IP in the new proposals. But we need to highlight the link between IP and treatment access, constantly. It needs to be raised every moment available. This is more or less the only way. This will help to convince the CCM members."*

Treatment activist in the EECA region



*"For the CCM, I'm not worried. I know how to convince them. We have to do it little by little. We need time to integrate, to understand the concepts. Little by little."*

Treatment activist in the MENA region



Jeed, a treatment activist and chairperson of the Thai Network of People Living with HIV (TNP+), Bangkok.

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## COMMON OBJECTIONS AND SUGGESTED RESPONSES

To help treatment activists convince the CCM and the writing team to include activities that increase access to quality and affordable medicines in Global Fund funding requests, the section below provides a list of common objections to these activities. For each objection, a suggested response is provided. The responses could be given by civil society CCM members, civil society members of the writing team, or other CCM observers who take part in meetings.

### Common CCM objection and suggested response #1



**When they say this:** “The Global Fund Board made a decision that it does not fund IP activities”

**You say that:** “Actually, there is no official Board decision or directive on this issue. There is nothing written that says the Global Fund Board has advised against funding IP work. In fact, activities that increase access to quality and affordable medicines are explicitly mentioned in several Global Fund policies.”



### Common CCM objection and suggested response #2



**When they say this:** “We don’t have any more funding available in our allocation to include your IP, A2M or health budget advocacy activities.”

**You say that:** “There is no limit on what we can include in the PAAR. At the very least, let’s put the IP, A2M or health budget advocacy activities there. They might be funded at a later date with Global Fund top-up funding or through grant savings.”



### Common CCM objection and suggested response #3



**When they say this:** “We have to take these activities out of the funding request because our Fund Portfolio Manager told us to.”

**You say that:** “This is a country-owned and country-led process. We as the CCM are in control over the contents of our funding request. We just need to justify and rationalize why they are important. Let the technical review panel decide.”



#### Common CCM objection and suggested response #4



**When they say this:** “Our country is not listed on the Global Fund’s list of projected transitions. We don’t need to worry so much about sustainability planning or increasing domestic funding.”

**You say that:** “The Global Fund believes long-term sustainability is a key aspect of development and health financing, and that all countries, regardless of their economic capacity and disease burden, should be planning for and embedding sustainability considerations within national strategies, program design and implementation.”



#### Common CCM objection and suggested response #5



**When they say this:** “We can include these activities in the next funding request, when we are closer to actually transitioning”

**You say that:** “If we include these activities now, it will save us money in the long run. Remember, the Global Fund is very focused on cost-savings, efficiencies, and sustainability of the programs it invests in. We have to spend now to save later.”



#### Common CCM objection and suggested response #6



**When they say this:** “The Global Fund doesn’t fund strategic litigation. How can you use money meant for governments to take the government to court?”

**You say that:** “The Global does fund strategic litigation. It is written in the modular framework handbook under the scope of human rights intervention packages. Reforming intellectual property regulations and laws and regulatory frameworks for medicine registration is contained in its technical briefs, as well.”



## PART 9: TECHNICAL ASSISTANCE

Technical assistance (TA) may help you to formulate and position activities that increase access to quality and affordable medicines in Global Fund grants. Longer-term, or project mode, TA providers may even fund some of these activities, if they do not get included in the grants. Activists are encouraged to reach out to the following Global Fund-related TA programs:



**TECHNICAL ASSISTANCE OPPORTUNITY:** The **Global Fund's Sustainability, Transition and Efficiency Strategic Initiative**<sup>39</sup> supports several assignments related to procurement and access to medicines, including TA to assess the feasibility to use international platforms for procurement anti-TB drugs and ARVs (i.e. Global Drug Facility, UNICEF) and to do reviews/amendments of legislation.



**TECHNICAL ASSISTANCE OPPORTUNITY:** The **UNAIDS Technical Support Mechanism**<sup>40</sup> supports TA assignments for strengthening the sustainability of effective programs. In the past, it has supported assignments to perform law and policy reviews, as well as drafting amendments to existing laws.



**TECHNICAL ASSISTANCE OPPORTUNITY:** The **Global Fund's Human Rights Strategic Initiative**<sup>41</sup> provides short-, medium- and longer-term technical assistance support for effective implementation of programs to reduce human rights-related barriers to services. Support is available for program design, planning, budgeting, implementation, developing capacity, identifying and making linkages to existing opportunities for scale-up, and developing M&E frameworks.



**TECHNICAL ASSISTANCE OPPORTUNITY:** The **Global Fund's Community, Rights and Gender Strategic Initiative** provides short-term, peer-led, support to civil society and community organizations to meaningfully engage in Global Fund country dialogue, funding request development, grant-making and implementation.



**TECHNICAL ASSISTANCE OPPORTUNITY:** The **GIZ BACKUP Health Initiative**<sup>42</sup> supports Consultancy Mode (< 6 months) and Project Mode (12 months +) assignments that aim to improve implementation of Global Fund programs. The projects can support the use of Global Fund grants to strengthen health systems, as well as management capacities of Global Fund grant recipients.



**TECHNICAL ASSISTANCE OPPORTUNITY:** The **French 5% Initiative**<sup>43</sup> provides Channel 1 (ad hoc) and Channel 2 (2-3-year projects) support to countries receiving Global Fund grants, to support them in the design, implementation and M&E. For 2019, priorities included: (1) Strengthening health systems at all levels (community to national) and (2) Access to care for vulnerable populations. CCMs, grant recipients and national-level organizations such as national aids councils or civil society networks can request support on a rolling basis for Channel 1, and when requests for proposals are issued for Channel 2.

## PART 10: ADDITIONAL RESOURCES

### GLOBAL FUND RESOURCES

Global Fund Funding Request Forms and Instructions

<https://www.theglobalfund.org/en/funding-model/applying/materials/>

Global Fund Modular Framework Handbook

[https://www.theglobalfund.org/media/4309/fundingmodel\\_modularframework\\_handbook\\_en.pdf](https://www.theglobalfund.org/media/4309/fundingmodel_modularframework_handbook_en.pdf)

Global Fund Cycles Video

[https://www.youtube.com/watch?v=VS\\_xclxjyUY](https://www.youtube.com/watch?v=VS_xclxjyUY)

iLearn Online Global Fund Learning

<http://www.theglobalfund.org/en/ilearn/>

Investing to End Epidemics: The Global Fund Strategy 2017-2022

[https://www.theglobalfund.org/media/2531/core\\_globalfundstrategy2017-2022\\_strategy\\_en.pdf](https://www.theglobalfund.org/media/2531/core_globalfundstrategy2017-2022_strategy_en.pdf)

Global Fund Sustainability, Transition and Co-Financing Policy

[https://www.theglobalfund.org/media/4221/bm35\\_04-sustainabilitytransitionandcofinancing\\_policy\\_en.pdf](https://www.theglobalfund.org/media/4221/bm35_04-sustainabilitytransitionandcofinancing_policy_en.pdf)

Global Fund Market Shaping Strategy (Annex 1 – Full Strategy)

[https://www.theglobalfund.org/media/4200/bm34\\_17-annex1marketshapingstrategy\\_paper\\_en.pdf](https://www.theglobalfund.org/media/4200/bm34_17-annex1marketshapingstrategy_paper_en.pdf)

Guide to Global Fund Policies on Procurement and Supply Management of Health Products

[https://www.theglobalfund.org/media/5873/psm\\_procurementsupplymanagement\\_guidelines\\_en.pdf](https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf)

Global Fund Breaking Down Barriers to Access Initiative

[https://www.theglobalfund.org/media/1213/humanrights\\_2016-removingbarrierspart2\\_qa\\_en.pdf](https://www.theglobalfund.org/media/1213/humanrights_2016-removingbarrierspart2_qa_en.pdf)

Global Fund Operational Policy Manual v. 2.23

[https://www.theglobalfund.org/media/3266/core\\_operationalpolicy\\_manual\\_en.pdf](https://www.theglobalfund.org/media/3266/core_operationalpolicy_manual_en.pdf)

Guidance Note: Sustainability, Transition and Co-financing of programs supported by the Global Fund

[https://eecaplatform.org/wp-content/uploads/2018/04/core\\_sustainabilityandtransition\\_guidancenote\\_en.pdf](https://eecaplatform.org/wp-content/uploads/2018/04/core_sustainabilityandtransition_guidancenote_en.pdf)

Technical Brief: Support to Effective Regulatory Systems for Procurement and Supply Management of Health products

[https://www.theglobalfund.org/media/8894/core\\_regulatorysystemsprocurementsupplymanagementhealthproducts\\_technicalbrief\\_en.pdf?u=637066545910000000](https://www.theglobalfund.org/media/8894/core_regulatorysystemsprocurementsupplymanagementhealthproducts_technicalbrief_en.pdf?u=637066545910000000)



Value for Money Technical Brief

[https://www.theglobalfund.org/media/8596/core\\_valueformoney\\_technicalbrief\\_en.pdf?u=637109743120000000](https://www.theglobalfund.org/media/8596/core_valueformoney_technicalbrief_en.pdf?u=637109743120000000)

Projected transitions from Global Fund country allocations by 2028: projections by component

[https://www.theglobalfund.org/media/9017/core\\_projectedtransitionsby2028\\_list\\_en.pdf?u=637104488100000000](https://www.theglobalfund.org/media/9017/core_projectedtransitionsby2028_list_en.pdf?u=637104488100000000)

## **ITPC AND PARTNER RESOURCES**

Advocacy for Community Treatment (ACT) Toolkit 2.0: Strengthening Community Responses to HIV Treatment and Prevention

<http://itpcglobal.org/wp-content/uploads/2015/02/ACT-Toolkit-2.0.pdf>

MENA IP Landscape

<https://itpcmena.org/wp-content/uploads/2017/10/e%CC%81tude-ITPC-ENG-HD-2.pdf>

Evergreening Patents Video

[https://www.youtube.com/watch?time\\_continue=1&v=G9CGZFFI1ww&feature=emb\\_title](https://www.youtube.com/watch?time_continue=1&v=G9CGZFFI1ww&feature=emb_title)

The Roadmap – Special Edition Report on Dolutegravir

[http://makemedicinesaffordable.org/wp-content/uploads/2017/08/DTG\\_Roadmap.pdf](http://makemedicinesaffordable.org/wp-content/uploads/2017/08/DTG_Roadmap.pdf)

The Roadmap – Special Edition Report on Tenofovir Alafenamide Fumarate (TAF)

<http://makemedicinesaffordable.org/wp-content/uploads/2018/05/Roadmap-SE-Report-on-TAF-2018-05-07F.pdf>

LACTA Community Advisory Board (CAB) – 2018 Report

<http://makemedicinesaffordable.org/wp-content/uploads/2019/06/Reporte-LATCA-CAB-F.pdf>

100% LIFE – 2018 Annual Report

[https://network.org.ua/wp-content/uploads/2019/06/report\\_2018\\_eng\\_web.pdf](https://network.org.ua/wp-content/uploads/2019/06/report_2018_eng_web.pdf)

## **OTHER RESOURCES**

Technical Support available through the UNAIDS Technical Support Mechanism

<https://www.opml.co.uk/projects/boosting-progress-in-fight-against-hiv-and-aids-in-africa-asia-and-the-pacific>

Technical Support available through the BACKUP Health Initiative (2015-2020)

<https://www.giz.de/expertise/html/19981.html>

Technical Support available through the French 5% Initiative

<https://www.initiative5pour100.fr>

The Global Price Reporting Mechanism for HIV, TB and malaria  
<http://apps.who.int/hiv/amds/price/hdd/>

The Medicines Patents and Licenses Database  
<https://www.medspal.org>

Beware the Procurement Cliff: Safeguarding supply of affordable quality medicines and diagnostics in context of risky transitions and co-financing  
[https://www.msfaccess.org/sites/default/files/2019-07/MSF\\_Brief\\_Global-Fund-Procurement-Cliff\\_2019.pdf](https://www.msfaccess.org/sites/default/files/2019-07/MSF_Brief_Global-Fund-Procurement-Cliff_2019.pdf)

Access to Medicines: The Role of Intellectual Property Law and Policy  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/02/ACCESS-TO-MEDICINES-THE-ROLE-OF-INTELLECTUAL-PROPERTY-LAW-AND-POLICY-1.pdf>

Glossary of Patent Terminology  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/02/GLOSSARY-OF-PATENT-TERMINOLOGY.pdf>

Patent Information and Transparency: A Methodology for Patent Searches on Essential Medicines in Developing Countries  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/02/Patent-Information-and-Transparency.pdf>

How to Conduct Patent Searches for Medicines  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/04/How-to-conduct-patent-search.pdf>

Overview of Patent Process  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/02/OVERVIEW-OF-PATENT-PROCESS.pdf>

Patents: Subject Matter and Patentability Requirements  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/02/The-TRIPS-Book-Patents.pdf>

Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/04/Guidelines-for-the-examination-of-pharmaceutical-patents.pdf>

Compulsory Licensing: Models for State Practices in Developing Countries, Access to Medicine and Compliance with the WHO TRIPS Accord  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/02/Compulsory-Licensing-Models-for-State-Practices.pdf>

Guidelines on Patentability and Access to Medicines  
[http://makemedicinesaffordable.org/wp-content/uploads/2016/02/Guidelines-on-Patentability-and-A2M\\_rev\\_EN.pdf](http://makemedicinesaffordable.org/wp-content/uploads/2016/02/Guidelines-on-Patentability-and-A2M_rev_EN.pdf)

TRIPS, Drugs and Public Health: Issues and Proposals  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/02/TRIPS-Drugs-and-Public-Health.pdf>

Patents and Access to Medicines: What Can Be Done at National Level  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/04/Patents-and-Access-to-Medicines.pdf>

Patents, Compulsory Licenses and Access to Medicines: Some Recent Experiences  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/02/Patents-Compulsory-Licences-and-Access-to-Medicines.pdf>

Malaysia's Experience in Increasing Access to Antiretroviral Drugs: Exercising the 'Government Use' Option  
<http://makemedicinesaffordable.org/wp-content/uploads/2016/02/Malaysia%E2%80%99s-Experience-in-Increasing-Access-to-Antiretroviral-Drugs.pdf>

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- <sup>19</sup> The 20 countries are: Benin, Botswana, Cameroon, Democratic Republic of Congo (province-level), Cote d'Ivoire, Ghana, Honduras, Indonesia (selected cities), Jamaica, Kenya, Kyrgyzstan, Nepal, Mozambique, Philippines, Senegal, Sierra Leone, South Africa, Tunisia, Uganda and Ukraine
- <sup>20</sup> See the Global Fund's website for more information on catalytic investment opportunities: <https://www.theglobalfund.org/en/funding-model/before-applying/catalytic-investments/>
- <sup>21</sup> Download **El Salvador's** April 2018 HIV Funding Request to the Global Fund here: [http://docs.theglobalfund.org/program-documents/GF\\_PD\\_001\\_81c69a81-4b47-4ef7-abf8-0c9bb9b615ea.zip](http://docs.theglobalfund.org/program-documents/GF_PD_001_81c69a81-4b47-4ef7-abf8-0c9bb9b615ea.zip)
- <sup>22</sup> Download **Belarus's** 2015 HIV Funding Request to the Global Fund here: [http://docs.theglobalfund.org/program-documents/GF\\_PD\\_001\\_e905b721-73ef-4102-9b55-3e3816fd39a7.zip](http://docs.theglobalfund.org/program-documents/GF_PD_001_e905b721-73ef-4102-9b55-3e3816fd39a7.zip)
- <sup>23</sup> Download **Kyrgyzstan's** March 2017 TB/HIV Funding Request to the Global Fund here: [http://docs.theglobalfund.org/program-documents/GF\\_PD\\_001\\_17fb0f65-7e83-4986-a312-e1c235aba132.zip](http://docs.theglobalfund.org/program-documents/GF_PD_001_17fb0f65-7e83-4986-a312-e1c235aba132.zip)
- <sup>24</sup> **The Central America-Dominican Republic Free Trade Agreement (CAFTA-DR)** is composed of the United States and Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua.
- <sup>25</sup> Download **Guatemala's** February 2018 HIV Funding Request to the Global Fund here: [http://docs.theglobalfund.org/program-documents/GF\\_PD\\_001\\_570af916-ae54-48b9-985b-3ba93401cf32.zip](http://docs.theglobalfund.org/program-documents/GF_PD_001_570af916-ae54-48b9-985b-3ba93401cf32.zip)
- <sup>26</sup> Download **India's** May 2017 TB Funding Request to the Global Fund here: [http://docs.theglobalfund.org/program-documents/GF\\_PD\\_001\\_1ceb0088-1404-434c-a467-edaafa54fa29.zip](http://docs.theglobalfund.org/program-documents/GF_PD_001_1ceb0088-1404-434c-a467-edaafa54fa29.zip)
- <sup>27</sup> Download **Thailand's** August 2017 TB/HIV Funding Request to the Global Fund here: [http://docs.theglobalfund.org/program-documents/GF\\_PD\\_001\\_84b1b0aa-8427-4964-b2e4-2b4cfc3d98b.zip](http://docs.theglobalfund.org/program-documents/GF_PD_001_84b1b0aa-8427-4964-b2e4-2b4cfc3d98b.zip)
- <sup>28</sup> Download **Kazakhstan's** May 2017 TB/HIV Funding Request to the Global Fund here: [http://docs.theglobalfund.org/program-documents/GF\\_PD\\_001\\_a0361ace-2024-4f42-8379-e911db84824b.zip](http://docs.theglobalfund.org/program-documents/GF_PD_001_a0361ace-2024-4f42-8379-e911db84824b.zip)
- <sup>29</sup> Download **Uzbekistan's** March 2017 TB/HIV Funding Request to the Global Fund here: [http://docs.theglobalfund.org/program-documents/GF\\_PD\\_001\\_41ed52bd-7ebe-4ebb-b6eb-a803555edfed.zip](http://docs.theglobalfund.org/program-documents/GF_PD_001_41ed52bd-7ebe-4ebb-b6eb-a803555edfed.zip)
- <sup>30</sup> A "**buyers' club**" is a club organized to pool members' collective buying power, enabling them to make purchases at lower prices than are generally available, or to purchase goods that might be difficult to obtain independently.
- <sup>31</sup> Download **Ukraine's** May 2017 TB/HIV Funding Request to the Global Fund here: [http://docs.theglobalfund.org/program-documents/GF\\_PD\\_001\\_5bf6447e-c475-4d00-afc3-7455e6f520fd.zip](http://docs.theglobalfund.org/program-documents/GF_PD_001_5bf6447e-c475-4d00-afc3-7455e6f520fd.zip)
- <sup>32</sup> Information from this lesson learned comes from the Global Fund's Technical Review Panel feedback to South Africa. This information is not publicly available. It is summarized here for the purpose of the toolkit.
- <sup>33</sup> Save the Children (2019) Health Sector Budget Advocacy: A guide for civil society organizations. Online at [https://www.who.int/pmnch/media/news/2012/201205\\_health\\_sector\\_budget\\_advocacy.pdf](https://www.who.int/pmnch/media/news/2012/201205_health_sector_budget_advocacy.pdf)
- <sup>34</sup> Information in this success story comes from a presentation delivered by the Global Fund at the Fourth Learning and Sharing Forum of the LAC Platform, 18-21 July 2019 in Mexico City, Mexico. Bonilla, P. (2019). Sustainability, Transition & Co-financing (STC): Progress & Ongoing Challenges [PowerPoint slides]. Online at [https://plataformalac.org/wp-content/uploads/2019/07/LAC-Platform-Presentation\\_2019-07\\_ENG.pdf](https://plataformalac.org/wp-content/uploads/2019/07/LAC-Platform-Presentation_2019-07_ENG.pdf)
- <sup>35</sup> Information in this success story comes from key informant interviews with Equal International, and from the meeting report from the High-Level Meeting on the Hepatitis C and harm reduction needs of people who use drugs and other key populations in South Africa.
- <sup>36</sup> Information in this success story comes from key informant interviews with ITPC-EECA, currently implementing project in Russia, Belarus, Armenia and Kazakhstan.
- <sup>37</sup> WHO (2011). The Global Price Reporting Mechanism for HIV, TB and malaria. Online at <http://apps.who.int/hiv/amds/price/hdd/>
- <sup>38</sup> Medicines Patent Pool. The Medicines Patents and Licenses Database. Online at <https://www.medspal.org>



- <sup>39</sup> All countries eligible for Global Fund grants could be eligible for TA through this Strategic Initiative.
- <sup>40</sup> Over 50 countries across Africa, Asia, and the Pacific are eligible. Requests need to be made through UNAIDS country offices.
- <sup>41</sup> The Human Rights Strategic Initiative has a specific focus on the 20 priority countries in the Global Fund's "Breaking Down Barriers to Access Initiative": Benin, Botswana, Cameroon, Democratic Republic of Congo (province-level), Côte d'Ivoire, Ghana, Honduras, Indonesia (5-10 cities), Jamaica, Kenya, Kyrgyzstan, Nepal, Mozambique, Philippines, Senegal, Sierra Leone, South Africa, Tunisia, Uganda, and Ukraine.
- <sup>42</sup> Eligible countries for GIZ BACKUP Health Initiative Technical Assistance: Burkina Faso, Cambodia, Cameroon, Colombia, Côte d'Ivoire, Democratic Republic of the Congo, Ethiopia, Guinea, Kyrgyzstan, Liberia, Malawi, Namibia, Nepal, Niger, Nigeria.
- <sup>43</sup> Eligible countries for French 5% Initiative Technical Assistance: Albania, Armenia, Benin, Bulgaria, Burkina Faso, Burundi, Cambodia, Cameroon, Cape Verde, Chad, Comoros, Congo, Costa Rica, Cote d'Ivoire, Democratic Republic of Congo, Djibouti, Dominica, Dominican Republic, Egypt, Ethiopia, Gambia, Gabon, Georgie, Ghana, Guinea-Bissau, Guinea, Equatorial Guinea, Haiti, Kosovo, Laos, Lebanon, Liberia, Madagascar, Mali, Mauritius, Morocco, Mauritania, Moldova, Montenegro, Mozambique, Niger, Central African Republic, Romania, Rwanda, Sao Tome and Principe, Saint Lucia, Senegal, Serbia, Thailand, Togo, Tunisia, Ukraine, Vanuatu and Vietnam.

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