

## Background Paper

# Access to Medicines

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## Introduction

The affordability, availability, and financing of medicines and other health commodities has always been a central issue for the Global Fund to Fight AIDS, Tuberculosis and Malaria, its donors, recipient countries, and affected communities. Given the significant amount and proportion of Global Fund grant funding that goes to health commodities procurement (up to 40 percent of annual grant disbursements), the strategic and operational components of their procurement and price strategies, and the availability of suppliers and access to their products, are key not just to ensure availability and affordability, but also future fund-raising initiatives.

These strategies are now under increased focus due to internal and external challenges. The new funding model specifically requires the Global Fund to look for better value for money in procurement, in what increasingly looks like a technical approach to what is essentially a deeply political issue. While the availability of low cost generic medicines for antiretrovirals (ARVs) has proven to be the most powerful and reliable way to reduce drug prices, prices of newer ARVs and treatments for multi-drug resistant tuberculosis (MDR TB) and hepatitis C are rising due to increased patenting, which excludes or limits the availability of low cost generic production and supply generally and the ability to procure improved formulations (e.g fixed dosed combinations or child friendly formulations) where they are only made by generic producers. This issue is most immediately felt by middle-income countries (MICs) and Global Fund graduating countries, which are faced with withdrawal of donor funds, unaffordable pricing strategies from patent holders and general exclusion from voluntary licenses (where they exist) for generic supply. But it also affects least developed countries (LDCs) where patent restrictions at national level and in key generic-producing MICs can prevent importation and local production.

Without generic competition and specific measures to ensure the continued availability of generic production and supply, prices for newer drugs will not come down the same way that they did for the first generation of medicines. Since its creation in 2002, the Global Fund has encouraged recipients of its funding, and provided technical and political support, to apply national laws and applicable international obligations in the field of intellectual property, including the flexibilities provided in the TRIPS Agreement (which provided measures to overcome patent barriers to generic production) in a manner that achieves the lowest possible price for products of assured quality.<sup>1</sup> A study by the Global Fund in 2010, on prices for a medicine to treat HIV, Lopinavir/ritonavir, demonstrated that countries, made substantial savings by switching to generic medicines, including through the use of TRIPS flexibilities, with price reductions ranging from 45 percent to 71 percent, against the price offered by the originator.<sup>2</sup>

However, current and proposed Global Fund policies have created a growing concern that the Global Fund is fundamentally altering its approach to access to medicines (A2M). There appears to be a progressive roll back of its previous position of the promotion of generic competition as a key driver for lowering costs, to a more opaque, centralized, collaborative approach with both generic producers and originators that risks reducing individual country ownership and threatening the continued supply of low cost generic production. In addition,

given the increasingly global spread of patenting, it is critical to also explore additional ways to challenge (and overcome) the high prices of, in particular, the newest medicines.

In light of these concerns, advocates should explore whether and how to expand activities in relation to the Global Fund to AzM issues more broadly. To help promote that debate this paper provides a preliminary identification of five potential areas which illustrate these concerns, and where the Global Fund's present or future policies could either enhance or limit the potential to use generic competition, rights-based advocacy, and/or its public purchasing power to lower the price of key medicines:

1. Development of a new market shaping strategy;
2. e-marketplace;
3. Equitable Access Initiative;
4. Global Steering Committee on Quality Assurance and;
5. the Global Fund's lack of public engagement in key external debates on the use and protection of TRIPS flexibilities.

It also identifies some of the formal opportunities for advocacy within these areas. It ends by suggesting some key questions that will need to be addressed as part of the discussions.

## I. Global Fund Internal Policies and Practices

### Market shaping

The core of the Global Fund's work on access to medicines, is undertaken by the procurement team, under the direction of Christopher Game.<sup>3</sup> In response to the new funding model's requirement to look for better value for money, the procurement and pricing department is already undergoing significant changes in structure, approach, personnel, and oversight of activities. His team is also leading the work to developing a new market shaping strategy to replace the current 2011 Market Shaping Strategy, which will feed into the overall Global Fund strategy.

The department has been reorganized, a larger team created and the work rebranded under the term the Procurement for Impact 'P4i initiative.' The P4i's stated aim is to 'increase access to products by fundamentally changing the way that the Global Fund works across the supply chain.'

At the November board meeting it was decided to abolish the existing market dynamic advisory board and that no new advisory body would be created or utilized to support the Board and its Committees. Oversight is now split between two committees: the Strategy, Investment and Impact Committee (SIIC), which will be responsible for guiding and overseeing the development and updating of strategic policies related to market-dynamics matters, including the new Market Shaping Strategy; and the Finance and Operational Performance Committee (FOPC), which will be responsible for oversight of the implementation of strategic policies.

The development of its market shaping role will be undertaken in collaboration with experts contracted by the Secretariat and with several partners: In June 2014, the Global Fund and UNITAID signed a memorandum of understanding (MoU) to allow for more collaboration in market shaping and access interventions. The Global Fund also formalized a collaboration with PEPFAR, which will include developing aligned procurement strategies. As collectively the Global Fund and PEPFAR procure over US \$1 billion of ARVs, they will be dominant purchasers for ARVs, and the approach adopted will shape the market for all purchasers. Another key partner is the Bill and Melinda Gates Foundation which is described as a ‘key thought partner’ with the Secretariat on market dynamics and supply chain issues. From late 2014, the Gates Foundation has funded a dedicated resource in the sourcing department who will help develop the approach to market shaping.

There is concern about how this market shaping role is and will be developed. Market shaping is an ambiguous term without an agreed definition, and can cover a range of interventions, some of which are already used by the Global Fund (e.g. pooled procurement, competitive tendering, splitting tenders), which can have both positive and negative ripple effects depending on the market situation and the intervention used. It is not solely about lowering prices; the idea is to use strategic interventions to address problems of availability, affordability and supply. Market shaping interventions can be applied to markets for both generic and patented medicines, to both demand and supply, and at different stages.

Although UNITAID is seen as the main external ‘thought leader’ on the subject,<sup>4</sup> market shaping is increasingly championed by the Gates Foundation, which has funded groups to work on the issues, supported the market shaping work of GAVI (such as the Advance Market Commitment (AMC) for the pneumococcal vaccine) and was a major contributor to a recent report from USAID which sought to identify emerging ‘best practices.’<sup>5</sup> There are clear differences in the approach taken especially to patent barriers to generic competition. Some such as GAVI, USAID, and the Gates Foundation have tended to define market shaping in a more limited way. They do not explicitly mention patent barriers or the use of TRIPS flexibilities and preference for negotiating with patent owners, while others, such as UNITAID and traditionally the Global Fund, recognizing that generic competition has been shown to be one of the most effective market shaping strategies in terms of lowering prices, have taken a broader approach including identifying and supporting mechanisms such as the use of TRIPS flexibilities to directly address patent barriers. Given the existence of patent barriers to generic competition for some medicines, particularly for MICs, there is concern about whether the Global Fund will retain this broad based approach to market shaping going forward.

#### **P4i: The ‘New Approach’**

Presentations on P4i and current activity give some indication of what the changes will mean in practice and the potential future direction of the Global Fund’s market shaping activities. The intention is to centralize most of the key activities within the Global Fund. This approach is illustrated in a Global Fund slide in Annex 1. The nature of the relationship with suppliers will change. The aim is to ‘open collaborative supplier relationships to drive innovation and reduce cost.’ The effect is to ‘in-house’ the majority

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of the previous outsourcing of procurement, with the Global Fund having direct relationships with both suppliers and procurement services agents (PSAs). This ‘pooled disbursement’ is intended to ‘leverage fragmented spend to extract and reward better behavior.’ They will offer long term ‘framework’ supply contracts, with volume guarantees, to selected preferred suppliers, based on multiple requirements from multiple countries and direct payment by the Global Fund to suppliers. These contracts will be awarded based on ‘open book negotiation’ (i.e. as part of the tender processes suppliers will have to provide details of their costs and proposed prices).

There has been no detailed discussion of what interventions will be used in relation to patented medicines, where there is either no generic production or restrictions on production or supply. Some presentations have referenced negotiating with patent owners (the Global Fund has said that it is already in discussion with some companies in relation to hepatitis C medicines) and on policies to ‘transition’ to generic competition based on a collaborative approach.

## Issues

There can be benefits to a centralized, collaborative, and coordinated approach (especially for small and fragmented markets such as for pediatric ARVs). However this approach raises a number of issues:

1. The potential downsides to long-term supply contracts: The theory is that by offsetting some supplier risk with a purchase agreement, the Global Fund can negotiate lower prices and better terms. While such contracts can have benefits in the short term, there can be negative long-term effects. Tensions could arise between affordability and availability; locking in prices may result in too high or too low a price being paid; lower prices and margins may drive suppliers out of the market; non-preferred suppliers may exit and it may discourage new suppliers from entering. The trade-offs inherent in this approach are ultimately decided solely by the Global Fund, which given its near monopoly power, especially for ARVs, will have massive ramifications not just for the Global Fund but also for other potential purchasers.
2. It is unclear if this approach will be applied to patented medicines. The bargaining power of the purchaser based on reference prices, volume, and market guarantees can be useful where generic competition is possible. However, when a medicine is patented the patent owner has the monopoly power, and the elements that increase the bargaining power for the purchaser do not exist in the same way. Seeking price discounts solely by negotiating with patent owners has historically failed to deliver the low prices available from generic supply in the ARVs market. The difficulties of successfully negotiating long-term supply agreements have been recently highlighted in the much-critiqued GAVI negotiation of an AMC for a pneumococcal vaccine.<sup>6</sup> It is also unclear how the fact that the availability of negotiated prices as well as whether a certain medicine is under a patent in a certain country is dynamic, differing from country to country, and dependent on the medicine in question and also evolving over time, will be factored in.

3. Lack of transparency and oversight: Key decisions will be made by the procurement team subject only to oversight from the SIIC and FOPC. It is not clear how any tradeoffs inherent in the different approaches will be made apparent and subject to sufficient input from countries, affected communities, and others. In discussion with the procurement team there has been some acceptance, particularly in relation to long-term contracts, that there may need to be new oversight mechanism(s), but there is no detail on what these would be and when any proposals would be produced.
4. Reduction of country ownership: These changes represent a massive centralization of power to the Global Fund. This can take away agency and capacity-building opportunities for the countries, as well as making strategic decisions or trade-offs about where to source (e.g. from local production, preferred suppliers for other non-Global Fund supported medicines). While the Global Fund has said that countries will be involved in designing the tender specifications, the Global Fund will undertake the ultimate design, negotiating, and selection. It is not clear how involved countries will be in these decisions. In the existing market strategy there is an explicit focus on market shaping that does not compromise country ownership, ‘identifying approaches the Global Fund can take to dramatically impact markets while enabling principal recipients and countries to retain the majority of decision-making related to procurement of health products funded by the Global Fund. By focusing on products that will not otherwise be available or affordable and time-limited interventions, this strategy is focused on choices between access or lack of access to life-saving products instead of a choice between local ownership and optimal value for money.’<sup>7</sup>
5. Absence of a clear intellectual property (IP) policy: Despite requests, the department has not developed an IP policy. In contrast to the 2011 market shaping strategy document, which specifically mentioned the issue of patent barriers and public support for the use of TRIPS flexibilities,<sup>8</sup> there is no explicit mention of either the existence of intellectual property barriers or methods to overcome them in current presentations, raising concerns that the Global Fund may exclude reference to the use of specific mechanisms to allow broad generic competition from its new market shaping strategy.
6. It is not clear whether the current use of TRIPS flexibilities by some of the Global Fund’s recipients will be undermined or stopped under a centralized system. The Global Fund’s good procurement practices encourage the recipients to apply TRIPS flexibilities in a manner that achieves the lowest possible prices for products of assured quality. These procurement guidelines apply to recipients; it is not clear whether the Global Fund’s own procurement department will apply those guidelines to themselves.
7. Lack of clarity about the relationship with UNITAID’s market shaping activities: The Global Fund-UNITAID collaboration is supposed to ensure that Global Fund procurement and market-shaping activities are informed by and aligned with UNITAID interventions. This can have a positive effect as UNITAID has a broader definition of market shaping. However, there have been reports that the United

Kingdom is pushing for the Global Fund to take over some of UNITAID's market shaping, raising concerns that the Global Fund's potentially conservative approach to market shaping will dominate UNITAID's more activist approach, (i.e. identifying patent barriers and strategies to overcome them and funding civil society groups to work on using TRIPS flexibilities).

### Potential advocacy opportunities

Under the oversight of the SIIC, the Secretariat plans to undertake a phased review starting in early 2015 of the current market shaping strategy based on the Technical Evaluation Reference Group (TERG) thematic review of market dynamics, and the TERG's additional thematic review of the Global Fund's role in shaping the market for pharmaceuticals and health commodities. The Secretariat's review will develop a proposal for how the Global Fund can improve, monitor, and evaluate its market shaping role in the future. The initial report is expected by the end of the first quarter of 2015 with the option for a follow-up report in the third quarter. Recommendations from this report will feed into the review of the market shaping strategy and work on the larger Global Fund strategy 2017-2021.

These reviews potentially provide an opportunity for advocacy on the need for an explicit requirement to evaluate and suggest mechanisms to overcome patent barriers; to more clearly articulate the market shaping approach (and generic competition's role within it) that will be adopted; how the inherent tradeoffs will be managed; specify the oversight mechanisms needed; and clarify the relationship between the market shaping activities of UNITAID and the Global Fund.

The first tender for ARVs under the new approach has just been completed and may provide another opportunity to ask about the approach and tradeoffs made.

## II. The E-Marketplace

### What is it?

A proposed online procurement platform for commodities, which has been described as an 'Amazon.com for aid.' While a number of questions remain about how exactly it will work, the idea is the e-marketplace would allow buyers (such as principal recipients 'PRs') to purchase drugs, prevention products (e.g. bed nets), testing supplies/lab equipment, administrative supplies (e.g. computers, office equipment) and other commodities (e.g. vehicles). The entire procurement process would be automated: buyers could search and compare prices, lead times, and quality across suppliers, then select and place orders. Payments could be directly made by the Global Fund to the suppliers after the order is placed, rather than by sending money to PRs to make the payments.

The idea has significant momentum and is being actively promoted by the Secretariat. The Gates Foundation has been the major "seed" investor to date. The Secretariat has interviewed some PRs, suppliers, partner donors, and agencies, many of whom they claim support the idea. Based on a series of assumptions, it has concluded that there is a

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compelling business case, for example that it would save \$250 million USD for the Global Fund alone over 5 years.

It has also embarked on a series of presentations to various stakeholders outlining the proposal and its benefits. The main potential risks mentioned in these presentations are only those connected with the functionality, use, and acceptance of the platform. While the initial focus would be on use by Global Fund recipients, the ultimate objective is ambitious and far reaching: that in the medium term the platform would be ‘spun off’ and made available to all to use, as a global public good, with the potential that it could become a main procurement tool used by multiple purchasers. In total, the initiative is presented as a way to ‘streamline drug procurement and result in cost-efficiencies—not just for the Global Fund, but for a variety of health commodities for all countries around the world.’

## Issues

There are undoubtedly positive aspects to the proposal: it could help to address some issues of long delays in drug procurement processes; increase some level of transparency about pricing and suppliers; and, depending on how it is used, more certainty for suppliers, both on demand and if countries choose to do so, greater transparency of calls for tenders, as it is proposed that countries ‘advertise’ such calls via the website. However:

1. It is a closed market. While it is described as an e-marketplace, in practice it is not an open market. The only prices and suppliers available for drugs will be those that have been pre-negotiated or cleared by the Global Fund procurement team; prices for other commodities are likely to be based on the e-catalogues used by other UN agencies. It will further consolidate and mainstream the centralizing of the procurement process in Geneva, outlined in the market shaping section above—with the negotiations about pricing and suppliers undertaken either by the Global Fund procurement team or other UN agencies. As with Amazon.com, PRs will only be able to see the prices available for their countries; they will not be able to see on this site whether or not their country’s price is more or less than another country’s, limiting both transparency and the potential negotiating position of PRs<sup>9</sup> and embracing a status quo in which prices are determined by external forces, and then are to be considered a given that is neither dynamic nor changeable.
2. It can increase the dependency of countries on the Global Fund and take away agency and capacity-building opportunities for the countries themselves to develop stronger skills in doing their own negotiations and procurement. While it is a voluntary mechanism, in reality if there is a sleek and easy website with drugs and pricing already pre-negotiated, and an arrangement that the Global Fund will just pay the drug supplier directly, the Global Fund is probably right to assume, as it does in its presentations, that many countries are unlikely to use their own resources to try and negotiate their own pricing instead.
3. While a concern for all countries, this can be a particular issue for graduating countries, who will not have access to the Global Fund negotiated prices (and potentially for other commodities) after they graduate. Although it is promoted as



being applicable to all countries, it is unclear how pricing and suppliers for transition and other ‘middle income countries’ will be able to be addressed and fed into this system. At worst it could just become a system to advertise and entrench company created tiered pricing policies without encouraging or enhancing the skills of countries to use alternative methods such as the threat or use of TRIPS flexibilities to help drive down drug prices.

4. It can limit advocacy opportunities. An automated system minimizes opportunities to enable civil society at a country level to take public action and advocate for the use of political levers and alternative strategies to help drive down drug prices.
5. Lack of clarity about oversight mechanisms. In addition to the general oversight provided by the SIIC, FOPC, and the Board, the Secretariat has stated that it is developing proposals for specific oversight mechanism(s), but proposals have yet to be developed, and to date the Secretariat has given no clear indication of what such mechanism(s) would be and which stakeholders would be involved in it.

### Potential advocacy opportunities

There is only a limited time window to seek to address these concerns. The formal next steps are for the Secretariat to produce two papers. The first on the work-to-date has been mentioned in various one-on-one conversations, but the date of release is not yet clear (possibly available by June 2015). The second will be about the forward-looking concept and it aims for it to be presented at the November board meeting for consideration/incorporation in the new Global Fund strategy. This second paper has yet to be drafted and as such is only likely to be available shortly before the meeting so there may be little time to analyze and influence it before it goes to the Board. On the assumption that the Board approves further development, the Global Fund will embark on a specific fundraising effort, probably with both public and private funders later this year. Initial estimated costs are in the region of \$12 million USD in 2015, for some of the background research/setting up systems/creating the web-platform. Running costs have yet to be quantified.

## III. The Equitable Access Initiative (EAI)

### What is it?

The EAI was convened by The Global Fund; GAVI; UNAIDS; UNICEF; UNDP; UNFPA; UNITAID; WHO; and the World Bank, and is co-sponsored by the Wellcome Trust<sup>10</sup> to develop new frameworks to better identify health needs and constraints to equitable access to health, including medical technologies and medicines, for countries as they transition from low-income to middle-income status. Its main expected output is a new country classification framework, which classifies countries by key components of equitable access to health, rather than solely based on GDP or other economic indicators, ‘in order to better inform national and international decision making processes on health and development.’

## Issues

The Global Fund, Mark Dybul in particular, and GAVI, have been the main drivers of the Initiative. The major concern has been that rather than looking at all options to facilitate affordable prices, the initiative, as originally described in Mark Dybul's report to the 30th Board Meeting, and in subsequent leaked TOR's,<sup>11</sup> showed that the Global Fund itself favored tiered-pricing as the main solution to access for MICs. As originally proposed, the Initiative would have tiered pricing 'hard-wired in as the single solution that the proponents continue to champion' and as such was 'a potential retreat from the time-tested pro-generic policies' which have been repeatedly shown to lead to lower prices than tiered pricing.<sup>12,13</sup> To a number of critics, the Initiative was seen as a modern version of the much criticized launch of the industry's first attempt to use tiered pricing as a solution to developing countries' access needs: the 2000 Accelerating Access Initiative (AAI), a collaboration of global regulatory bodies, UN agencies, and the pharmaceutical industry. Following protests from civil society groups the TOR was changed but there remain suspicions that (some variation of) tiered pricing may come back on the table as a primary solution.

While the focus has been on tiered pricing, the implications of the EAI work, if they do propose a new country classification system, is much wider than that, and would be hugely influential and could define the approach that the Global Fund and other agencies take both to procurement and funding eligibility criteria. This initiative therefore potentially affects current work on human rights issues for key populations, and broader A2M concerns.

## Potential Advocacy Opportunities

The work of the EAI will be undertaken by a high-level Expert Panel, a Technical Working Group with high-level representation from the public sector and civil society set up by the Convening Organizations, and a Project Management Team. The draft timeline for the EAI indicates that much of the work will be done by the technical working groups leading up to a final report in Feb 2016. In addition to the civil society representatives 'inside' the process, consultations (though it is not clear how and with whom) are due to take place with civil society and other organizations through the course of this year.

## IV. The Global Steering Committee on Quality Assurance

The Global Fund has been a major driver behind the establishment of The Global Steering Committee on Quality Assurance, (GSC-QA) which is a new coalition to 'combat falsified, substandard, stolen and diverted medicines and other health products.' Its initial members include the Global Fund, the U.S. President's Malaria Initiative, USAID, WHO, World Bank, GAVI, UNDP, UNITAID, and the U.S. Food and Drug Administration. Representatives from regulatory and law enforcement agencies, non-governmental organizations and the pharmaceutical industry will be also invited to join the GSC. The committee is due to meet quarterly under the chairmanship of Norbert Hauser, former Inspector General of the Global Fund.

Falsified, substandard, stolen, and diverted medicines can represent a public health threat, and action should be taken to prevent them. However, some civil society groups have raised concerns that this committee may turn into another forum, as with the now discredited multi stakeholder taskforce, the International Medical Product Anti-Counterfeit Taskforce (IMPACT), to promote policies that confuse legitimate generics with poor quality medicines and which both threaten the supply of quality generic medicines and divert resources from policies that would effectively address poor quality medicines. There is limited information available to show that this is a significant issue for Global Fund-supported projects, so it is unclear to what extent this should be a priority for the Global Fund itself.

### Potential Advocacy Opportunities

The Global Fund has responded to these initial concerns by stating that the GSC-QA will only focus on broader quality assurance activities, however given the history of this issue, some of the partners involved and previous initiatives, it would make sense to remain vigilant. It may be beneficial to explore those civil society groups who will be attending the next meeting as observers, whether further advocacy is needed now, for example, to obtain clear statements on the absence of IP issues and/or how a watching brief could be maintained on the Global Fund's and GSC-QA's activities in this area, in order to be able raise the alarm if needed and develop specific advocacy actions.

## V. Global Fund's Lack of Public Engagement in Key External Debates on the Use and Protection of TRIPS Flexibilities

As a major procurer of medicines, the Global Fund has a direct interest in, and can be a powerful voice in support of, activities that seek to protect the limited space for developing countries to mitigate the impact of patent protection on the production and importation of low-cost generic medicines. Yet, the Global Fund appears to be retreating from previous engagement on this issue, and has made no public statements in relation to key external debates such as:

- The use and protection of pro public health flexibilities within the TRIPS agreement. For example, the Global Fund has remained silent on the Least Developed Countries (LDC) Group's request to extend the 'pharmaceutical waiver' (where LDCs are not obliged to grant or enforce patents and data protection for pharmaceuticals) in the TRIPS Agreement. The waiver is set to expire on January 1, 2016 and the LDC group has requested it be extended until such time as the LDCs transition to developing country status. Due to the prevalence of primarily colonial era patent laws in many LDCs, this waiver has been extensively used to overcome patent barriers to the procurement of ARVs.<sup>14</sup> The waiver can also allow local production of generic versions of patented medicines in LDCs. In contrast to the Global Fund's silence, UNITAID and IDA (a Global Fund procurement agent) have both made public statements in support.

- Threats to generic competition such as ‘TRIPS +’ free trade agreements (FTAs) that seek to lengthen, strengthen, and broaden patent protections and introduce harmful enforcement measures that could restrict both generic product and the policy space for developing countries to utilize TRIPS flexibilities. In contrast, in 2011, the Global Fund issued a strong statement expressing concern over potential impacts of FTAs on access to medicines, the importance of generic production for the Global Fund, and support for the use of TRIPS flexibilities. The statement included the following:
  - “The Global Fund... joins its partners in calling for negotiating parties in Free Trade Agreements with developing countries to ensure that no provision in such agreements hampers access to lower-priced quality medicines.”
  - “In the case of on-going trade negotiations between the European Union and India, the Global Fund supports proposals to ensure that these agreements allow continued access to medicines, in particular, to treatments for AIDS, TB and malaria.”
  - “Free Trade Agreements with the developing world need to take into account that the world’s major pandemics predominantly affect the poorest people and should recognize the role of India in supplying quality low-cost medicines to the developing world,” said Professor Kazatchkine. Ninety-two per cent of antiretroviral drugs delivered through Global Fund grants in 2010 were produced in India.”<sup>15</sup>

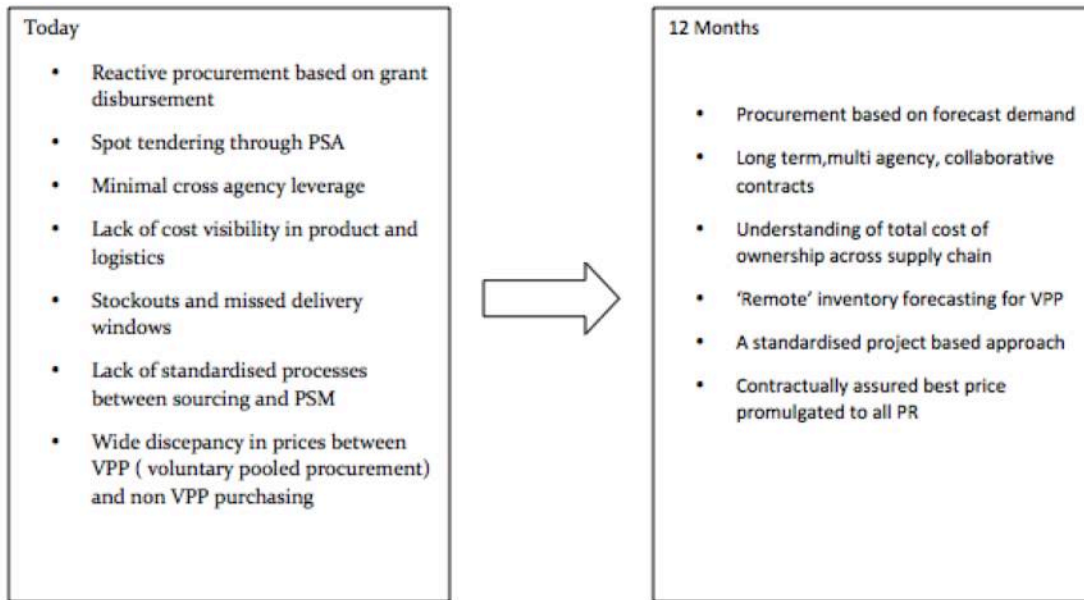
### Potential Advocacy Opportunities

The LDC waiver request is due to be discussed at the TRIPS council in June 2015, so there is still time for the Global Fund to make a supportive statement. Discussions on the EU-India FTA and the TPPA are ongoing, but with increased pressure to finalize them.

## VI. Conclusion

The overall goal of this briefing is to help advocates, and their key partners and allies engaging with the Global Fund to identify concerns about the Global Fund’s current and future approach to access to medicines; further work will be needed to investigate these concerns. There are both specific issues with particular proposals and a more general concern that in all areas the Global Fund is and will continue to fundamentally alter its approach to A2M: withdrawing from its previous position of the promotion of generic competition as a key driver for lowering cost to a more opaque, centralized, collaborative approach with both generic producers and originators that risks possibly reducing individual country ownership and threatening the continued supply, and production of low-cost generic medicines.

## Annex 1



Source: Adapted from Global Fund presentation 9 July 2013 – Innovation and Global ACT Supply Chain Threats Conference.

## Endnotes

<sup>1</sup> The GF procurement guidelines state at 3.3, 'Recipients will use their best efforts to apply national laws and applicable international obligations in the field of intellectual property including the flexibilities provided in the Trade- related Aspects of Intellectual Property Rights (TRIPS) agreement and interpreted in the Doha declaration, in a manner that achieves the lowest possible price for products of assured quality' Guide to Global Fund Policies on Procurement and Supply Management of Health Products (June 2012)

<sup>2</sup> Presentation by the Global Fund ( Logez, Casas) 'The Global Fund Experience : access to patent information and impact on procurement of medicines' February 2011

<sup>3</sup> [http://www.theglobalfund.org/en/mediacenter/newsreleases/2012-11-09\\_Global\\_Fund\\_Appoints\\_Christopher\\_Game\\_as\\_Chief\\_Procurement\\_Officer/](http://www.theglobalfund.org/en/mediacenter/newsreleases/2012-11-09_Global_Fund_Appoints_Christopher_Game_as_Chief_Procurement_Officer/)

<sup>4</sup> <http://www.unitaid.eu/en/how/market-approach>

<sup>5</sup> [http://www.usaid.gov/sites/default/files/documents/1864/healthymarkets\\_primer.pdf](http://www.usaid.gov/sites/default/files/documents/1864/healthymarkets_primer.pdf)

<sup>6</sup> <http://www.msfaccess.org/spotlight-on/advance-market-commitment>

<sup>7</sup> REPORT OF THE MARKET DYNAMICS AND COMMODITIES AD-HOC COMMITTEE: The Global Fund Twenty-Third Board Meeting GF/B23/9 Geneva, Switzerland, 11-12 May 2011

<sup>8</sup> [http://www.theglobalfund.org/en/mediacenter/newsreleases/2011-05-26\\_Global\\_Fund\\_strategy\\_aims\\_to\\_help\\_shape\\_market\\_and\\_ensure\\_sustainability\\_of\\_AIDS\\_treatment/](http://www.theglobalfund.org/en/mediacenter/newsreleases/2011-05-26_Global_Fund_strategy_aims_to_help_shape_market_and_ensure_sustainability_of_AIDS_treatment/)

<sup>9</sup> It is not clear if the prices paid by other countries will still be made available in other GF databases. Even if this is the case it will take addition effort to find this information as apparently there will be no click through via the e market place to other pricing databases.

<sup>10</sup> <http://www.theglobalfund.org/en/equitableaccessinitiative/>

<sup>11</sup> <http://www.ip-watch.org/2014/04/07/global-fund-and-tiered-medicines-pricing-under-debate/>

<sup>12</sup> <http://blogs.plos.org/speakingofmedicine/2013/12/01/is-the-global-fund-heading-backwards-on-access-to-medicines/>

<sup>13</sup> A Win-Win Solution? A Critical Analysis of Tiered Pricing to Improve Access to Medicines in Developing Countries <http://apps.who.int/medicinedocs/en/d/Js19031en/>

<sup>14</sup> T'Hoën, EM : The Global Politics of Pharmaceutical Monopoly Power 2009 P 63

<sup>15</sup> [http://www.theglobalfund.org/en/mediacenter/newsreleases/2011-05-26\\_Global\\_Fund\\_strategy\\_aims\\_to\\_help\\_shape\\_market\\_and\\_ensure\\_sustainability\\_of\\_AIDS\\_treatment/](http://www.theglobalfund.org/en/mediacenter/newsreleases/2011-05-26_Global_Fund_strategy_aims_to_help_shape_market_and_ensure_sustainability_of_AIDS_treatment/)

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