The Global Fund's Market Shaping Strategy, Procurement for Impact Programme and E-Marketplace

Médecins Sans Frontières (MSF) would like to share the following comments and recommendations concerning the Global Fund to Fight AIDS, Tuberculosis and Malaria's Market Shaping Strategy, Procurement for Impact (P4i) programme and E-Marketplace.

I. The Global Fund should implement internal and external checks and balances on the increasingly influential market shaping activities of the Sourcing Department to ensure public-health driven outcomes.

There has been a tremendous growth of the power and influence of the Sourcing Department, without appropriate checks and balances as a result of the following five factors:

1. There is a clear shift of the Sourcing Department from 'market dynamics' to 'market shaping'. The in-sourcing of various roles and responsibilities usually left to third parties has generated cost and transactional efficiencies, but it has also removed many third parties that could directly challenge or counter-balance the approaches sought by the Global Fund.
2. The Global Fund has signalled an interest in moving into areas normally reserved for UNITAID and the Medicines Patent Pool (MPP). It is important for the three entities to develop complementary strategies, and any such framework that lays out such complementarity is welcome. However, MSF does not support the Global Fund assuming the role of, or managing the work of, either organisation.
3. The Global Fund has increased consolidation of the market for key commodities across the entire value chain, most notably for antiretroviral medicines (ARVs), with the potential for increased control over medicines for tuberculosis (TB) and for relevant diagnostics. While such an approach may achieve short term fiscal gains, it may have unforeseen harmful, long-term repercussions. In addition, the Global Fund is vertically integrating the production of pharmaceuticals (from raw materials supply to formulation) as well as the eventual purchase of such products. With such power, any wrong choice can have far-reaching negative consequences.
4. The Strategy, Investment and Impact Committee (SIIC) and Finance and Operational Performance Committee (FOPC), as the two Committees charged with oversight of the Sourcing Department, are not adequate substitutes for the now-dissolved Market Dynamics Advisory Group (MDAG), especially due to the complexity of market shaping and the dynamic and ever-changing nature of the marketplace.
5. There is a lack of internal control over the Sourcing Department. A recent report of the Office of the Inspector General (OIG)[1], focused on the Sourcing Department, noted "a lack of a strong internal control framework including policies, resources, tools and systems to support effective implementation of activities and points to a lack of an effective control environment."

[1]See : http://www.theglobalfund.org/documents/oig/reports/OIG_GF-OIG-15-008_Report_en/

II. The Sourcing Department should provide a coherent strategy that explains the relationship between and overall impact of the Market Shaping Strategy, Procurement for Impact programme and the E-Marketplace.

Although the Sourcing Department has noted the close complementarity of its Market Shaping Strategy with the Procurement for Impact (P4i) programme (and ultimately the E-Marketplace), the Global Fund has not yet explained how these programs and strategies will work together to produce public-health driven outcomes, even though these efforts are all managed primarily under the Global Fund's Sourcing Department. MSF believes that any final strategy for each of these programmes must be brought under the aegis of one broader strategic approach. This will better hold the Global Fund accountable to key performance indicators and ensure that the board, relevant committees and the broader public health community can better work with the Global Fund to achieve shared outcomes. We note in particular the following two aspects:

1. The size of the Global Fund spend for certain commodities under P4i – in particular ARVs, and potentially diagnostics and TB drugs, means that the P4i program can be far more significant with respect to its impact on the global market than any specific Global Fund market shaping strategy. For some products, procurement under P4i may define the price and access for the product in most developing countries, and therefore, improved transparency and external oversight of the Sourcing Department is required to ensure the best possible outcomes.
2. The E-Marketplace is not clearly defined and has not been formally presented for approval or oversight. It has also been kept separate from the Market Shaping Strategy and P4i, in spite of the fact that how it aggregates demand, defines prices and manages procurement has obvious and direct impacts and linkages with the market shaping program and P4i. MSF believes any market shaping or procurement strategy adopted by the Global Fund Board must fully integrate and explain the role, function, purpose and transparent monitoring of the impact of the E-Marketplace.

The Global Fund should explain how these three programs will work together to achieve impact. The Global Fund should also take into account the fact that these activities require greater oversight and scrutiny to ensure the best outcomes.

III. The Global Fund must clarify and improve its approach to pricing.

Historically, the Global Fund has played a critical role in achieving the lowest possible prices for commodities, as well as eliminating intellectual property (IP) barriers that prevent generic competition for products in key manufacturing and importing countries.

However, in recent years, MSF has grown increasingly concerned that the Global Fund is moving towards pricing strategies that favour the commercial preferences of pharmaceutical companies and ignore the role of IP barriers, implemented now and in the future, in restricting access to affordable medicines.

In particular, MSF notes the following:

1. The Global Fund has not taken a sufficiently clear stance against tiered pricing. Last year, the Global Fund sought to connect the Equitable Access Initiative to tiered pricing policies and practices, an approach that would have validated the pharmaceutical industry's (branded and generic) commercial strategy to segment markets and maximise profits. The new strategy should clearly state that the Global Fund will seek to overcome tiered pricing – both through its own market strategy and through political engagement on this matter.

2. The Sourcing Department has expressed an interest in looking at value-based pricing for new commodities. Specific industry-based interpretation of value-based pricing can justify exorbitant prices for new commodities (such as medicines to treat hepatitis C) and therefore this should not be considered in such a manner by the Global Fund. The Global Fund also

should not consider only cost effectiveness as a means to determine which new technologies to focus upon for its programming, but rather as a marker to intervene when there are high prices. Most commodities used by the Global Fund exist within very dynamic markets – especially in developing countries – and therefore cost can be a flexible parameter.

IV. The Global Fund must continue to advocate for robust use of TRIPS flexibilities, warn against policies that will undermine generic competition, and enhance the efforts of the MPP and UNITAID to overcome IP barriers.

The Global Fund must take a strong stance on overcoming IP barriers, which is the structural cause of commercial pricing strategies that undermine access. IP barriers also limit important improvements to existing medical tools, such as field-appropriate formulations or fixed-dose combinations.

Early procurement strategy documents from the Global Fund encouraged countries to use TRIPS flexibilities. However, recently the Global Fund has failed to raise its voice during critical IP debates that will significantly affect generic competition worldwide. Two examples include a failure of the Global Fund to voice its support for an extension of a waiver requested by least developed countries to avoid implementation of TRIPS IP rules for medical tools, and a failure to voice any concerns with certain aspects of the Trans-Pacific Partnership Agreement, which threatens to be the single most harmful trade agreement with respect to access to affordable medicines.

It is encouraging that the Global Fund has tentatively indicated interest in working with UNITAID and the MPP on IP matters. Such cooperation is necessary and two aspects should be taken into account. Firstly that the Global Fund must not displace or undermine dynamic strategies applied by UNITAID or the MPP to overcome intellectual property barriers. Secondly, that the Global Fund should apply its market and political power to overcome IP barriers that neither UNITAID nor the MPP can address through existing tools and levers.

Overall, MSF recommends that the Global Fund adopt an IP strategy that includes the following three elements:

1. The Global Fund should support and enable the use of TRIPS flexibilities where required to facilitate access to generics for its procurement.
2. The Global Fund should publish clear analyses and explanations of the impacts that trade agreements or other trade policy processes will have on generic competition for Global Fund commodities.
3. The Global Fund should support the MPP politically as it negotiates voluntary licenses for key commodities to ensure such licenses support multiple producers in the market and expands access to generics for all low- and middle-income countries.

V. The Global Fund should maintain and expand its key role in improving the quality, safety and efficacy of medical tools.

MSF supports the Global Fund playing a key role in safeguarding and ensuring the quality, safety and efficacy of medical tools. MSF welcomes the close collaboration between the Global Fund and the World Health Organization (WHO) Pre-Qualification (PQ) programme. The WHO PQ programme and the Global Fund's Expert Review Panel initiatives are critical to ensuring and accelerating introduction of quality-assured products to the market. Still, the Global Fund can and should do more to ensure the sustainability of the WHO PQ programme.

While undertaking these efforts, the Global Fund should avoid engaging in activities, task forces or technical working groups which confuse legitimate generic medicines or solutions to address substandard medicines with industry-driven rhetoric and approaches to counterfeits that risk restricting access to legal generic medicines.

VI. The Global Fund should support efforts to improve innovation in ways that are within the organization's current mandate.

In recent months, the Global Fund has expressed a stronger interest in ensuring a pipeline of new products, regimens and product presentations. This would represent a significant further evolution of the Global Fund, from market dynamics to market shaping to research and development (R&D).

The Global Fund should not get involved in upstream R&D or activities, and especially the Global Fund should not do so by artificially increasing prices for pipeline products in order to incentivize development of new products. MSF also believes it is outside the remit of the Global Fund to articulate patient needs – this should be led by WHO as a part of its norm-setting role. However, the Global Fund may have a role in contributing to such exercises when target product profiles are developed by the WHO.

Procurement by the Global Fund could play an important role providing an additional 'pull incentive' for manufacturers without the Global Fund expanding its mandate. In particular, when responding to country preferences for particular product presentations or formulations, the Global Fund could design tenders that include preferential (and transparent) procurement strategies to scale up a superior product presentation. In addition, the Global Fund could play a proactive role in presenting manufacturers the market dynamics for particular products, including the 'time to market'. Finally, the Global Fund could provide assistance to countries to adopt new technologies, including new formulations and presentations.

VII. The Global Fund should consider adapting supply chain preferences and increasing support for last mile delivery.

Countries need increased support in 'last mile' delivery of medicines from central depots to rural clinics. This includes capacity building, training, human resource allocations, transport, communications and technological necessities to ensure medicines make it to the patients who need them. Consequently, Global Fund indicators should include availability of drugs at health posts and clinics, not just at the central level. In geographically larger countries with significant proportions of the population accessing care in rural areas, there also needs to be an assessment of supply chain segmentation with innovative solutions to address the different issues in rural areas as compared to urban.

The Global Fund preference for a 'pull' supply chain system versus a 'push' supply chain system is concerning, since no single solution fits all contexts. While a pull system may lead to reduced wastage in some contexts, it also leads to stock-outs as many countries do not have the capacity to support this type of system. Without at least one pharmacy technician in every health facility, it will be quite difficult to implement practically.

One solution is to use an 'informed push' system, whereby staff at clinics and health posts send information regarding number of patients seen and average monthly consumption (AMC) of medicines to Central Medical Stores, where the data is analyzed and stock is 'pushed' to the clinic based on their needs. This system allows increased responsibility of the health care works at the clinics but decreases the risk of stock rupture. Mismatching the supply chain design with the skills of health care workers will only further complicate a system that needs to be simplified to be successful.[2] Standardization of software and forecasting tools is also essential.

Finally, ensuring stock availability such that patients are able to receive at least three months of ARVs should be a minimum guarantee. Returning to the clinic monthly (or more often) interferes with the patient's work and family commitments and is an increased burden for health care workers.

[2]Yadav, Prashant. Health Product Supply Chains in Developing Countries: Diagnosis of the Root Causes of Underperformance and an Agenda for Reform. Health Systems and Reform, 1(1) :98-110, 2015

VIII. The Global Fund should provide expertise and capacity building to support product forecasting.

Recognizing the positive impact of the consortium for pediatric anti-retrovirals, the Global Fund should facilitate joint initiatives that allow clear forecasting for specific health products with other international purchasers, including UN agencies, countries, donors or non-governmental organizations. This is particularly important where there are new commodities or changes anticipated, for example due to changes in international recommendations. In parallel, in short-term intervals – for example, on a quarterly basis – the Global Fund should produce product forecasts and provide an open platform for accessing information on procurement volumes. Today, there are clear problems with forecasting and quantification on the ground and this continues to result in stock outs. It is useful for the Global Fund to lend expertise to this area. However, it will be crucial for the Global Fund to support capacity building and system strengthening in countries as well.

IX. The Global Fund should help consolidate markets and pool procurement, including for 'transitioning' countries, with appropriate conditions.

Consolidating markets is useful for specific commodities for which there is insufficient demand or a fragmented market, as with paediatric ARVs and point-of-care early infant diagnostics. Such consolidation can provide benefits with respect to price, quality and procurement.

As discussed above, there can be tangible short-term benefits for the Global Fund to assume and use a dominant market position to negotiate lower prices for large markets. At the same time, as the Global Fund becomes the only or one of a few buyers in the market, the risk of market distortions also increases dramatically.

As such, the Global Fund should have a balanced approach to leveraging its market power so that it does not inadvertently curtail competition by awarding tenders to a few suppliers. Pooling procurement can have important and positive effects on pricing. However, there is a concern that consolidating procurement may also result in a dangerous reduction in the number of manufacturers – risking eventual price increases which may also result in product stock-outs. Given the size and nature of procurement for key commodities, it is important that such procurement is conducted transparently so that board members, relevant committees, civil society and affected governments can provide adequate oversight and accountability. While MSF agrees that volume-based discounts and international procurement have benefits, the Global Fund should act with the knowledge and commitment that generic competition, in addition to volume-based discounts, is critical to making products more affordable.

Finally, as countries start to 'transition' from the Global Fund, there is a question as to whether and how the Global Fund should work with such countries. Generally speaking, MSF supports the Global Fund extending its negotiated prices to such countries. However, certain requirements must accompany this extension, namely:

1. It must be offered on an opt-in basis
2. The Global Fund must act on IP barriers in those countries when they arise, whether on-going barriers for products, or to provide institutions support to overcome policy barriers (such as free trade agreements) - which threaten these countries.
3. The Global Fund must avoid tiered pricing.

X. The Global Fund should address key questions and concerns prior to implementation of the E-Marketplace

MSF has a number of questions, in addition to recommendations regarding the E-Marketplace. The E-Marketplace should provide a clear explanation of how it interfaces with the Global Fund Market Shaping Strategy and P4i programme. Through our initial engagement, we have identified a range of other potential concerns, including:

1. The E-Marketplace could introduce tiered pricing.

2. The E-Marketplace could be a closed market wherein the only prices on offer are those negotiated by the procurement team at the Global Fund.
3. Countries may not be able to negotiate prices outside of the E-Marketplace due to its size and visibility, leaving them with few options except to comply with the prices, rules and approach used by the E-Marketplace.
4. The E-Marketplace could undermine, not build, country ownership over procurement and supply chain management, which are critical components of a well-functioning drug management system.
5. The E-Marketplace could limit or completely remove the role of advocacy to reduce prices, especially by civil society, which has played and continues to play a key role in bringing down prices for key medicines used by the Global Fund today.

In addition, MSF has key questions about the E-Marketplace which remain unanswered, including:

1. The governance and oversight of the program, especially given concerns with oversight of existing Global Fund market-shaping activities
2. The nature and extent of support by the Global Fund for in-country capacity for procurement, and whether such training and capacity will be available if countries choose not to use the E-Marketplace.
3. The relevance or applicability of the E-Marketplace for countries after they 'transition'.

XI. Conclusion

MSF appreciates the Global Fund as a key player in ensuring access to medicines for populations around the world, including the patients we serve through our medical operations. However, the current proposals of the Global Fund must incorporate lessons learned from past successful and failed strategies. The Global Fund must ensure that any expansion of role and influence is done in a manner that builds upon successes, ensures transparency and buy-in, and avoids unintended consequences that undermine access to medicines for patients in need.