**MSF Access Campaign**
**Policy Brief**
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# BEWARE THE GLOBAL FUND PROCUREMENT CLIFF

## Safeguarding supply of affordable quality medicines and diagnostics in context of risky transitions and co-financing

## BACKGROUND

For the last two decades, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) has helped to scale up access to affordable, quality-assured medicines and diagnostics that have saved millions of lives. However, this progress is under threat. Following stagnating donor funding globally[1], the Global Fund has in recent years revised its policies that determine funding for countries, including its funding allocation methodology[2] and its Sustainability, Transition and Co-financing (STC) policy[3]. As a result, countries are shifting from Global Fund-supported mechanisms to national processes for the purchase of medicines and diagnostics for the three diseases.

Médecins Sans Frontières (MSF) believes this shift is often premature and poses significant risks to people's access to quality medicines and diagnostics, with dire implications for people with HIV, tuberculosis (TB), or malaria. Higher prices, use of medicines of unknown quality, and supply interruptions increase the risk of death from these preventable, treatable diseases, and exacerbate the growing global health crisis of drug-resistant infections. The policy changes also threaten to reverse progress made in ensuring critical innovations to fight these diseases are introduced as swiftly as possible.

The Global Fund's revised allocation methodology[2] prioritises funding for countries with the highest disease burdens and lowest incomes. Countries that are deprioritised and experience funding reductions as a result often face pressure to more rapidly mobilise alternative (predominantly domestic) funds for activities previously supported by the Global Fund – often in the absence of a rigorous assessment of procurement challenges and financial capacity. Furthermore, the revised STC policy[3] requires all countries, even those with the lowest incomes, to increase their co-financing of disease programmes, including through purchasing medicines and diagnostics. While countries may already purchase medical products for a range of health issues, the shift to increased national purchasing processes for HIV, TB and malaria products risks the loss of a number of the benefits associated with Global Fund support, namely lower prices, quality assurance and stable supply.

Countries that are ready to play a larger role in purchasing medical tools for their populations should do so. However, the shift away from Global Fund supported processes is complex and must be managed carefully; failures directly affect people's health and lives.

## RISK #1: AFFORDABILITY

The benefits of Global Fund-supported purchasing processes have been achieved largely through the Global Fund Pooled Procurement Mechanism (PPM) for HIV and malaria, and through the Stop TB Partnership's Global Drug Facility (GDF) for TB. These pooled orders result in higher volumes by aggregating demand, attracting multiple suppliers offering competitive prices. By contrast, individual countries require smaller volumes, which fragments demand and draws fewer suppliers or fails to interest manufacturers altogether. Purchasing medical products using national processes therefore reduces competition among suppliers and leaves countries with substantially less negotiating power – leaving them vulnerable to paying higher prices.

### Global Fund-supported purchasing processes enable:

**LOWER PRICES due to:**
- Volume-based price reductions
- Competition across multiple suppliers
- Price transparency
- Value-added tax (VAT) exemption

### National purchasing processes risk:

**HIGHER PRICES due to:**
- Small markets/volumes
- Less competition
- Lack of price transparency
- Loss of VAT exemption

**Lack of access to volume-based price reductions:** Pooled procurement across 139 countries through GDF enabled a savings for countries of approximately US$31 million between April 2018 and March 2019.[4] Outside of Global Fund support, not all countries can continue to access pooled procurement mechanisms or have the negotiating power to secure the most affordable prices on their own. In the case of Georgia, an exemption to national law was approved to allow purchasing of TB medicines and diagnostics with state funds through GDF.

**Less competition:** High volumes facilitated by the Global Fund attract additional manufacturers to the market, including generics companies. This generates competition and generally lowers prices. Lower prices resulting from competition may no longer be available for many countries that shift to national purchasing processes.

**Challenges with national tenders:** As countries shift away from Global Fund-supported purchasing processes, their national purchasing laws often require a competitive tendering process. However, as MSF has observed, national tenders may only attract a few suppliers, resulting in higher prices, or tenders being unanswered altogether because the size and requirements of the tender are unattractive to manufacturers.

**Lack of price transparency:** Price negotiations between individual countries and manufacturers take place bilaterally, and pharmaceutical corporations will always try to maximise profits through higher prices. Final negotiated prices are not always made publicly available. As a result, countries risk paying higher prices based on income status or individual negotiation strategies and have no way to benchmark against the prices other countries are paying. There are ongoing efforts to address this issue globally; a resolution adopted at the 72nd World Health Assembly urged governments to improve drug price transparency.[5]

**Lack of VAT exemption:** Products that are considered 'free' – such as those sourced through Global Fund mechanisms – are exempt from VAT. When countries purchase the same products through national purchasing processes, they are no longer considered free and may no longer receive VAT exemptions, although countries should exempt medicines from VAT. Since VAT for these medicines must be paid with domestic funds allocated in the national budget, this can reduce the overall budget available for these medicines and thereby increase the per-person cost of treatment.

In an assessment of TB procurement and supply issues linked to national procurement processes, GDF has documented a number of affordability challenges linked to shifts to national purchasing processes. As shown in Table 1, between October 2016 and October 2018, 21 low- and middle-income countries purchased TB medicines and diagnostics that far exceeded the lowest global prices that they would have paid if purchasing via GDF. Furthermore, eight low- and middle-income countries experienced failed tenders during the same period.[6] There is no equivalent documented accounting for the risk of increase in prices for HIV products as a result of the shift to national processes.

## RISK #2: QUALITY

Another negative consequence of these policy shifts relates to the quality of medicines. Medicines purchased with Global Fund support must comply with the organisation's stringent Quality Assurance (QA) Policy[7], which ensures that medicines and diagnostics meet international standards for quality, safety and efficacy. The QA policy requires medicines to be prequalified by the World Health Organization (WHO) Prequalification Programme (PQ) or authorised for use by a stringent drug regulatory authority (SRA). Since most national purchasing processes do not require WHO PQ or SRA approval, and some regulatory authorities may not have the capacity to fully assess the quality and safety of medicines, national purchasing processes introduce the risk of purchasing products of unknown quality. Over the 24-month period of the GDF assessment of TB procurement and supply issues, 29 low- and middle-income countries purchased medicines of unknown quality, and five purchased diagnostics of unknown quality (see Table 1).[6]

**Global Fund-supported purchasing processes enable:**

**QUALITY due to:** WHO/SRA quality standards

**National purchasing processes risk:**

**UNKNOWN QUALITY due to:** WHO/SRA quality standards not routinely required

## RISK #3: SUPPLY

Finally, another benefit of Global Fund-supported purchasing processes is that they circumvent the problem of corporations failing to register products in countries that are considered unattractive markets. When countries transition from Global Fund support, or gradually assume greater responsibility for procurement with domestic funds, not all countries efficiently issue import waivers for unregistered medicines and diagnostics, creating delays in supply. In addition, Global Fund purchasing mechanisms support countries with demand forecasting and better ensure a sustainable supply.*

GDF has documented an alarming number of TB medicine stock-outs in countries required to shift from Global Fund-supported purchasing to national purchasing processes. From October 2016 to October 2018, 15 low- and middle-income countries experienced medicine stock-outs (see Table 1).[6]

**Global Fund-supported purchasing processes enable:**

**SUSTAINABLE SUPPLY due to:** Import waivers

**National purchasing processes risk:**

**UNSUSTAINABLE SUPPLY due to:**

- Loss of import waivers
- Fewer suppliers

* Global Fund also has an emergency order function, which transitioning countries should be able to access if needed – including with domestic funds.

Table 1: TB procurement and supply issues linked to national procurement processes, October 2016 to October 2018[6]

| Issue | No. of Countries | Regions |
|---|---|---|
| Stockouts (medicines) | 15 | Africa, Asia, EECA |
| Failed Tenders (medicines, lab consumables and reagents) | 8 | Africa, Asia, EECA |
| Medicines of unknown quality | 29 | Africa, Asia, EECA, Latin America |
| Diagnostics of unknown quality | 5 | Asia, EECA |
| Medicines and diagnostics not recommended by WHO | 6 | Africa, Asia, EECA |
| High medicine and diagnostic prices | 21 | Africa, Asia, EECA, Latin America |

> "The problems with procurement are not new, but because of the switch from global to national procurement systems, the problems are more numerous. The number of TB stockouts is alarming."
>
> **- BRENDA WANING, CHIEF, GDF**

# RECOMMENDATIONS

The challenges faced by countries shifting from Global Fund support to national purchasing processes threaten people's health and survival. To collectively address these challenges, the Global Fund, affected countries, donor countries and WHO must urgently implement the following mitigation strategies:

## GLOBAL FUND

1. **ASSESS:** Conduct and act upon risk and readiness assessments for countries undergoing transition or increasing their co-financing commitments. Exempt countries from co-financing commitments for the purchasing of medicines and diagnostics if/when issues are identified.
2. **ENSURE TRANSPARENCY:** Promote and enable the sharing of co-financing agreements, timelines and readiness assessments, particularly with key stakeholders and implementing partners.
3. **PROVIDE POLICY FLEXIBILITIES AND SAFEGUARDS** in relation to Global Fund co-financing agreements and facilitate access to GDF, PPM and the Global Fund emergency procurement mechanism.
4. **ESTABLISH A SAFETY NET:** Make available dedicated additional funds and resources to respond rapidly to avert stockouts, for example by providing emergency supply of medical products when problems arise linked to shifts to national procurement systems.
5. **SUPPORT ADOPTION OF PRO-ACCESS POLICIES:** Based on readiness assessments, explore options to provide countries with technical support and capacity-building to address regulatory and procurement challenges.
6. **MONITOR & REPORT** on relevant and clearly identified national impact and coverage indicators, including scale-up of testing, prevention and treatment services that could be negatively affected by the transition to national procurement systems.

## AFFECTED COUNTRIES

1. **ENSURE AFFORDABILITY:**
   - Revise purchasing requirements to allow the use of international pooled mechanisms (such as the PPM or GDF) for certain lifesaving products.
   - Ensure transparency throughout the purchasing and tendering process, including by publishing final agreed prices and other commitments as outlined in the World Health Assembly resolution on drug price transparency.[5]
   - Utilise TRIPS flexibilities and other safeguards to encourage additional suppliers, increase competition, lower prices, and better ensure sustainable supply.
   - Remove VAT and any other taxes, tariffs and distribution mark-ups on medicines and diagnostics.
2. **ENSURE QUALITY:** National tenders should include quality-assurance requirements such as WHO PQ/SRA approval.
3. **REMOVE BARRIERS TO IMPORTATION:**
   - Join the WHO Collaborative Registration Procedure (CRP)* to facilitate national registration of medicines.
   - Enable expedited registration of WHO PQ-prequalified or SRA-approved medicines.
   - Use import waivers while national registration for certain lifesaving products is pending.

## DONOR COUNTRIES

1. Fund the Global Fund to meet targets for the sixth replenishment, covering the period 2020-2022.[9]
2. Support affected countries in establishing strong purchasing processes and practices, and fund mechanisms that help countries to optimise these processes (specifically WHO PQ and the CRP).
3. Support civil society in playing a 'watchdog' role to ensure transparency of national purchasing processes and supply of affordable, quality-assured medicines and diagnostics.

* The WHO CRP expedites the registration process, targeting 90 days for national registration of WHO PQ-prequalified and SRA-registered products, though manufacturers must still submit a registration file at country level.

## WHO

1. Broadcast risks and document problems related to Global Fund transition and co-financing arrangements.
2. Support regional or cluster pooled procurement strategies for affected countries.
3. Advocate for use of WHO PQ and CRP by manufacturers and affected countries.
4. Promote price transparency through updates to the Global Price Reporting Mechanism.
5. Update WHO's "Operational principles for good pharmaceutical procurement" as guidance for affected countries.[10]

## MSF'S EXPERIENCE

Over the past 12 months, MSF has also witnessed problems linked to the accelerated shift to national purchasing processes following changes in Global Fund policies and funding decisions.

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.

In Guinea, where financial and health systems are still recovering from the 2014-2016 Ebola outbreak, the supply of HIV antiretroviral drugs was interrupted largely due to Global Fund co-financing expectations that exceeded the capacity of national financial and purchasing systems.

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