TANA Netting
Procurement of Sub-standard Long-Lasting Insecticidal Nets

GF-OIG-21-001
26 February 2021
Geneva, Switzerland
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1. Investigation at a glance

1.1. Executive Summary

This investigation concerns TANA Netting FZ-LLC (TANA), a manufacturer and supplier of Long-Lasting Insecticidal Nets (LLINs). OIG received information that between January 2017 and April 2018, TANA manufactured LLINs using unapproved manufacturing methods to bind insecticide to the net, and that there had been a deliberate attempt to falsify manufacturing data to cover up the non-conformity. The nets suffered from considerable loss of insecticide after washing, resulting in unpredictable performance during their lifespan.

In violation of OIG’s access rights, TANA failed to provide OIG with manufacturing data and records. This impeded OIG’s ability to identify evidence of data falsification and fraud at the factory level, meaning OIG had to draw its conclusions using retrospective laboratory testing.

TANA did not adhere to approved manufacturing requirements and failed to control product quality of over 52 million Dawa Plus 2.0 LLINs costing US$106m, in violation of the Supplier Framework Agreement. Following this investigation, the Global Fund Secretariat and its Recoveries Committee will take account of nets manufactured from January 2017 to January 2019 to seek a recoverable amount and/or contractual remedies.

OIG review of grant Principal Recipients (PRs) and Secretariat processes established that red flags relating to the TANA net non-conformity went unchallenged. Quality control testing performed on the TANA nets did not follow WHO quality requirements.

1.2. Genesis and Scope

In November 2018, TANA reported that between January 2017 to April 2018, its sister company HSNDS used an unapproved chemical formula to manufacture LLINs. The nets had a reduced life span and were outside of the required product specification, due to being under dosed with insecticide. As a result, TANA could not guarantee the quality of approximately 60 million LLINs delivered to its clients during this time. TANA reported that HSNDS manufacturing records had been falsified to cover up the non-conformity. OIG subsequently opened an investigation.

After receiving TANA’s report, the Global Fund suspended all existing orders for new LLINs with the firm, moving planned orders to other contracted suppliers. 21 countries had received affected nets: Afghanistan, Angola, Benin, Ghana, Guinea, Laos, Kenya, Madagascar, Mali, Mozambique, Myanmar, Niger, Nigeria, Pakistan, Philippines, Rwanda, Somalia, South Sudan, Sudan, the Democratic Republic of Congo and Zambia.

The Global Fund worked with partners within the impacted countries to assess the public health benefits/risks of deploying the DAWA Plus 2.0 nets that had already been procured. The Global Fund decided to retain the nets that had already been distributed, to ensure populations were protected, and organized quality control testing to determine the actual level of the nets’ non-conformity with requirements.

OIG’s Investigations Unit visited Pakistan in October 2019, examining available records and interviewing TANA and HSNDS employees.

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1 LLIN is a factory-treated mosquito net made of material into which insecticide is incorporated or bound around the fibers. The net must retain its effective biological activity for at least 20 WHO standard washes under laboratory conditions and 3 years of recommended use under field conditions. WHO Guidelines for malaria vector control, 2019.
1.3 Context

Mosquito nets act as a physical barrier, preventing insect bites. Adding insecticide to nets enhances protection, killing or disabling mosquitoes through contact with the chemical. LLINs are one of the most cost-effective forms of malaria control, and The Global Fund has vastly expanded access to them. In the countries where the Global Fund invests, bed net coverage for at-risk populations increased from 30% in 2010 to 51% in 2018.

All grant Principal Recipients must procure nets that comply with World Health Organization (WHO) quality requirements. For nets procured through the Global Fund’s Pooled Procurement Mechanism (PPM), the PPM procurement agent is responsible for ensuring WHO compliance. When PRs procure LLINs themselves, they are responsible for ensuring compliance. In each case, the PR or the PPM procurement agent must arrange quality control testing and report the results to the Global Fund.

From 2009 onwards, TANA supplied over 121 million LLINs under Global Fund grants, at a cost of US$261 million. Between January 2017 and April 2018, the Global Fund purchased 52 million Dawa Plus 2.0 LLINs from TANA for US$106 million: 28 million nets bought through the Global Fund’s PPM, and 24 million through grants to PRs.

Figure 1: Global Fund expenditure on TANA nets, by country (Jan 2017 - Apr 2018)

In February 2013, TANA commissioned H. Sheikh Noor-ud-Din & Sons Pvt. Ltd (HSNDS), a manufacturer, to produce Dawa Plus 2.0 bed nets. Both TANA and HSNDS are part of NRS International, a family-owned holding company (Annex A details the interlinkages between the family companies). By 2017, HSNDS was producing up to 300,000 nets a day.

In October 2018, the HSNDS Board appointed a new CEO of HSNDS. A month later, TANA reported to the Global Fund that HSNDS had used an unvalidated chemical formula to produce the bed nets. In January 2019, TANA ceased bed net production and transferred ownership of the Dawa Plus 2.0 product to Moon Netting FZE. Neither TANA nor Moon Netting are current Global Fund contracted suppliers.

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The Pooled Procurement Mechanism is a Global Fund strategic initiative that aggregates order volumes on behalf of participating grant Recipients to negotiate prices and delivery conditions with manufacturers.

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1.4 Summary of Findings

- TANA did not control the manufacturing processes of its nets, resulting in sub-standard products.
- TANA and HSNDS obstructed the OIG investigation and failed in their contractual obligation to produce manufacturing data and documentation.
- Quality control testing of TANA LLINs did not follow WHO guidelines.
- Global Fund Quality Assurance mechanisms were ineffective in identifying non-compliance.

1.5 Impact of the investigation

TANA did not adhere to approved manufacturing requirements and failed to control the quality of over 52 million nets, valued at over US$106 million. As this is a breach of contract, the Global Fund has the right to seek an appropriate refund. In such cases, the Secretariat’s Recoveries Committee proposes to the Executive Director what management actions to take or contractual remedies to seek. Given the manufacturer’s records were destroyed and only limited retrospective testing was conducted, it is difficult to assess the true number and value of nets that did not meet specifications. In this case, to determine a recoverable amount, the Committee will consider available testing results, countries’ acceptance of Dawa Plus 2.0 nets manufactured from January 2017 to January 2019, and the actual costs of their shipment, storage, and disposal, where applicable.

Following this investigation, the Secretariat has stipulated that suppliers must inform the Global Fund of any critical deficiencies identified. It has also strengthened the requirements of manufacturers’ quality management systems, use of subcontractors, and product quality requirements within framework agreements.

The Secretariat has allocated US$750,000 to support the WHO in product assessments and onsite inspections of LLIN manufacturing. It is also working with WHO and the President’s Malaria Initiative on the review of Insecticide-Treated Nets (ITN) efficacy through a comprehensive landscaping study. The Secretariat aims to report the findings in the first half of 2021.

The Secretariat has selected a panel of suppliers to undertake quality assurance, quality control and risk management services, and is revising its operational guidelines for pre-shipment inspection, sampling and testing.

Global Fund Quality Assurance capacity and processes will be further improved through Agreed Management Actions, with the Secretariat agreeing to:

- review Principal Recipient and PPM procurement agent compliance with Global Fund Quality Assurance requirements verifying whether recent LLIN procurements from other suppliers were at risk;
- provide guidance on pre-shipment inspections, sampling, and testing LLINs, and check whether testing activities performed by PRs and procurement agents comply with Global Fund quality control testing requirements;
- design and roll out a market surveillance program, and update applicable Procurement and Supply Management policies and guidance;
- define responsibilities and operational mechanisms to enforce Quality Assurance compliance.

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3 As required by the Supplier Framework Agreement and the Code of Conduct for Suppliers.

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2. Findings

2.1 TANA and HSNDS prevented the OIG from establishing the full extent of non-conformity and wrongdoing

TANA and HSNDS obstructed the OIG investigation by failing to provide access to records and data.

The Global Fund’s Code of Conduct for Suppliers required TANA “… to maintain accurate and complete records … of all financial and business transactions under Global Fund-financed contracts for a minimum period of five years after the date of last payment.” The Global Fund’s Supplier Framework Agreement required TANA to maintain accounting books, records, documents and other evidence for at least three years after their last payment.

OIG asked TANA for access to records and data between January 2017 and April 2018 to establish whether wrongdoing contributed to the quality issues with the Dawa Plus 2.0 LLINs. TANA directed OIG to HSNDS, who explained that hard copy records and electronic data, computer hard drives, e-mail and electronic logistics management information system (eLMIS) data servers had been destroyed or removed from the HSNDS factory around August 2019 by the former management team, led by the former HSNDS CEO. Current HSNDS employees corroborated this, stating that the previous management removed all IT infrastructure from the factory when they left. With their departure, HSNDS also lost access to the e-mail domain it was using at the time.

The former HSNDS management dispute this, however, saying all records and data were left behind on the premises, and that they physically handed over TANA and HSNDS e-mail and eLMIS system servers to the new CEO. OIG confirmed that the former CEO handed over possession of the HSNDS factory, but there is no detail or inventory to specify what else was handed over. Despite the vital importance of these missing records and data, neither TANA nor HSNDS demonstrated that they were taking any action to recover them. TANA told OIG that they had taken all possible actions to provide the necessary records.

The full extent to which TANA nets did not conform to specifications is unknown.

In the absence of manufacturing records and data, TANA could not demonstrate whether the Dawa Plus 2.0 nets manufactured by HSNDS between January 2017 and January 2019 complied with WHO specifications. Flaws in HSNDS manufacturing and quality control processes (detailed in Finding 2.2) suggest a controls failure. Without the books and records, it was impossible for OIG to identify whether or when HSNDS started using an unvalidated chemical formula and production method, as reported by TANA.

The Global Fund retrospectively tested the quality of available TANA nets against WHO specifications for the chemical and physical properties of LLINs. Samples from 56 batches (12,406,957 nets) of undistributed Dawa Plus 2.0 LLINs manufactured between July 2017 - January 2019 were quality tested during May – November 2019. TANA agreed to cover the cost incurred by the Global Fund in testing these nets.

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4 As defined in section 4.7 of the Global Fund Policy to Combat Fraud and Corruption.
5 Quality assurance, quality control, procurement and supply chain records and data, emails and other correspondence between TANA and HSNDS related to or referencing the manufacture (production methods), formulation used for LLIN chemical dipping and quality control of Dawa Plus 2.0 LLINs; records showing how and when TANA formally communicated to HSNDS the WHO approved recipes and relevant production methods for Dawa Plus 2.0.

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6 A batch of TANA nets consists of the output of 24 hours across all stentors (fabric treatment machines), or up to approximately 250,000 nets.
7 These batches were tested for the following WHO specifications for Dawa Plus 2.0 LLINs: deltamethrin content, deltamethrin wash resistant index (WRI), fabric weight, WRI and deltamethrin content stability at elevated temperature after storage.
The testing found that 11 of 13 batches manufactured from January 2017 to April 2018 (2,225,388 nets) were below WHO specifications. Of 43 batches produced after April 2018, 40 batches (9,172,803 nets) fell below WHO specifications. OIG estimates that TANA sold 11,398,191 substandard LLINs to Global Fund Recipients, almost 92 percent of the nets tested during the investigation, in violation of the Supplier Framework Agreements.

TANA accepted testing results which found two batches (321,564 nets) supplied to Guinea and Togo to be substandard. Regarding other results, TANA argued that there are limitations in quality control testing for nets which have been in storage for a prolonged period. Some samples tested (e.g., in South Sudan) were obtained from nets that had been transported and stored in extreme storage conditions; TANA argued that manufacturer guarantees do not apply to improperly stored nets.

In organizing quality testing of the TANA nets during the investigation, the Global Fund considered WHO specifications that provide an international point of reference against which products can be judged.

HSNDS could not assure that Certificates of Analysis for the TANA nets were genuine.

WHO stipulates that as a supplier of public health pesticides, TANA must provide a Certificate of Analysis (CoA) to prove each product batch complies with product specifications at the time of delivery.\(^8\) HSNDS CoAs issued for TANA nets manufactured between January 2017 and January 2019 confirmed that batches were within WHO specifications. HSNDS reported testing all completed batches and sending the testing results to TANA by e-mail for review and approval.

HSNDS issued CoAs only after receiving TANA’s written approval and denied fabricating information. TANA and HSNDS could not provide supporting documentation and correspondence to evidence how HSNDS tested the nets, and whether the testing results were accurately reflected in the CoAs.

\(^8\) WHO Guidelines for procuring public health pesticides, March 2012.
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2.2 TANA did not control the manufacturing processes of its nets, resulting in substandard products

Supply chain, manufacturing processes and quality control and quality assurance processes at HSNDS were flawed. TANA failed to control and ensure the required quality of the Dawa Plus 2.0 LLINs manufactured by HSNDS.

TANA massively increased its production capacity at the HSNDS factory, from 10-15,000 nets per day at the start of 2017 up to 300,000 nets a day at the end of the year. In December 2017, the Director of TANA learnt that HSNDS had not ordered the expected volumes of binder chemicals to manufacture Dawa Plus 2.0 nets. He subsequently established that HSNDS used non-approved chemicals and combinations to manufacture the nets from January 2017 to April 2018.

A former HSNDS manager told OIG that HSNDS had been using the unapproved formula throughout 2017 and until 5 April 2018, but could not say when the recipe was changed, or by whom. He said he had witnessed deficient fabric, which should have been rejected, being used to manufacture TANA nets. He said the former CEO of HSNDS was not knowledgeable about manufacturing of LLINs or quality issues.

Another HSNDS manager confirmed to OIG that some nets manufactured in 2017-2018 failed quality standards. The OIG also gathered witness testimony of weaknesses that could have significantly impacted the quality of the HSNDS-produced nets, such as raw fabric being stored uncovered and exposed to sun and rain, the use of uncalibrated scales to measure binders and pesticides, and untested water being used for net manufacturing.

In its response to OIG’s investigation findings, TANA acknowledged that it lost control over production due to control and governance issues. TANA said it did not gain financially from the matter, and that it has invested significantly in improving its production processes.
2.3 The Global Fund’s quality control mechanisms are inadequate, and ineffective in identifying substandard LLINs

A Global Fund Operational Policy Note, “Implementing the Quality Assurance Policies for Pharmaceutical, Diagnostics and Other Health Products,” stresses the importance of ensuring that grant recipients procure quality-assured health products. A team of three in the Supply Operations Department provides support to ensure compliance with quality assurance policies and requirements.

**Deficient quality control impeded the identification of non-conforming nets.**

To ensure that procured LLINs comply with WHO quality requirements, the Global Fund requires grant Principal Recipients and the PPM procurement agent to arrange pre-shipment inspection and quality control testing according to WHO-approved specifications and methods, and to report the results to the Global Fund. WHO recommends that three nets should be taken randomly from every batch, and that all the nets’ physical and chemical properties should be analyzed.

While the PPM procurement agent and PRs arranged pre-shipment quality control testing of TANA LLINs manufactured between January 2017 and April 2018, those tests did not identify the nets’ non-conformity, leading to them being considered eligible for procurement. There were inefficiencies in the testing method:

- Whereas in the majority of reviewed cases the PRs tested each batch of a multi-batch consignment, the PPM procurement agent only tested one batch per consignment.

- The PPM procurement agent did not test the nets for stability at high temperatures, or for Deltamethrin wash resistant index after storage at high temperature, as required by WHO guidelines. The PRs tested these two parameters inconsistently.

**Oversight weaknesses in Global Fund Quality Assurance processes.**

OIG’s 2019 Annual Report highlighted the risk of weak quality assurance processes, observing that there is only limited assurance that product quality is maintained throughout the supply chain, until products are dispensed to beneficiaries.

This investigation found that PRs inconsistently provided quality control testing data to the Global Fund. Pre-shipment testing reports for the Dawa Plus 2.0 nets manufactured between January 2017 and April 2018 were not readily available, and had to be requested from the PPM procurement agent or PRs during the investigation.

Some testing reports could not be provided at all. For example, the Global Fund Secretariat could not confirm whether it received pre-shipment testing results for 5.7 million Dawa Plus 2.0 nets procured directly from TANA by a PR in Kenya, at a cost to the Global Fund of US$13.8 million.

The Secretariat acknowledged that no procedures were in place to monitor whether the procurement agent and PR were providing quality control testing results to the Global Fund. An Agreed Management Action will address this key control weakness through the design and implementation of guidance for pre-shipment inspection.

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9 Ibid.
10 Deltamethrin is a synthetic insecticide (a chemical product that kills insects) and an active ingredient of Dawa Plus 2.0 nets. WHO specifications and evaluations for public health pesticides, July 2017.
sampling and testing of LLINs, post-market surveillance, and a verification process of LLIN quality control testing practices by PRs and the procurement agent.

In May 2018, an OIG investigation of the Secretariat’s Quality Assurance team’s effectiveness in overseeing PR procurements of HIV rapid diagnostics testing kits and obtaining value for money found that purchases of non-compliant RDT kits worth US$230,268 were not identified\textsuperscript{11}. The Secretariat subsequently agreed to clarify its quality assurance mandate, including the necessary activities, roles and responsibilities; however, the relevant Agreed Management Action, due on 30 June 2019, has not yet been implemented.

As previously noted by OIG audits, given the material investment of Global Fund resources in health products, and the significant programmatic ramifications of poor-quality health products, there is a critical need for the Secretariat to evaluate the overall framework for the quality assurance of health products from an end-to-end perspective. A comprehensive quality framework and monitoring are needed to provide better assurance that the Secretariat’s programs and investments are as effective as possible.

\textbf{The Secretariat was aware of quality issues with Dawa Plus 2.0 LLINs as early as November 2017.}

On 14 November 2017, the Global Fund’s Quality Assurance team issued a Rapid Risk Assessment Report regarding an identified non-conformity with WHO specifications (deltamethrin WRI) of 11 batches of TANA’s DAWA Plus 2.0 LLINs, procured through the PPM procurement agent for Rwanda. The Quality Assurance team recommended increasing the sampling size for the quality control of TANA nets procured, going forward.

In June 2018, re-testing of two batches (304,700 nets) of Dawa Plus 2.0 manufactured by TANA and supplied to Afghanistan found them to be non-compliant with WHO specifications. The Quality Assurance team identified that the failure of the PR’s procurement agent to test the nets against the full set of WHO specifications was a root cause for these substandard LLINs being procured without detection.

The Quality Assurance team conducted a full risk assessment of these reported quality issues, concluding that the testing was inadequate. The PPM procurement agent and PR in Afghanistan were recommended to increase the sampling size, but there was no follow-up action.

\textsuperscript{11} GF-OIG-18-010 Proactive Investigation of Procurements of Non-Compliant HIV Rapid Diagnostic Testing Kits.

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3. Global Fund Response

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<th>Agreed Management Action</th>
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<td>1. Based on the findings of the report, the Global Fund Secretariat will finalize and pursue, from all entities responsible, an appropriate recoverable amount. This amount will be determined by the Secretariat in accordance with its evaluation of applicable legal rights and obligations and associated determination of recoverability.</td>
<td>31 December 2021</td>
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*Owner: Chair, Recoveries Committee*

| 2. The Secretariat, in consultation with the OIG, will report findings of supplier misconduct for potential referral to the Sanctions Panel.                                                                                           | 30 September 2021 |

*Owner: Head, Supply Operations*

| 3. The Secretariat will review and report on PRs and the PPM procurement agent’s compliance with the Global Fund Quality Assurance requirements for the period July 2019 - June 2020.                                                | 30 September 2021 |

*Owner: Head, Supply Operations*

| 4. Based on the findings of the report, the Global Fund Secretariat will formalize: 1) guidance for the pre-shipment inspection, sampling, and testing of LLINs; 2) guidance for post market surveillance that covers all Insecticide-Treated Nets procured through the Global Fund; 3) internal verification process of the ITN quality control testing practices by the PRs and the PPM procurement agent. | 31 December 2021 |

*Owner: Head, Supply Operations*
Annex A: Interlinkages between the NRS International group of companies
Annex B: Methodology

**Why we investigate:** Wrongdoing, in all its forms, is a threat to the Global Fund’s mission to end the AIDS, tuberculosis and malaria epidemics. It corrodes public health systems and facilitates human rights abuses, ultimately stunting the quality and quantity of interventions needed to save lives. It diverts funds, medicines and other resources away from countries and communities in need. It limits the Global Fund’s impact and reduces the trust that is essential to the Global Fund’s multi-stakeholder partnership model.

**What we investigate:** The OIG is mandated to investigate any use of Global Fund funds, whether by the Global Fund Secretariat, grant recipients, or their suppliers. OIG investigations identify instances of wrongdoing, such as fraud, corruption and other types of non-compliance with grant agreements. The Global Fund Policy to Combat Fraud and Corruption\(^{12}\) outlines all prohibited practices, which will result in investigations.

OIG investigations aim to:

(i) identify the nature and extent of wrongdoing affecting Global Fund grants;
(ii) identify the entities responsible for such wrongdoing;
(iii) determine the amount of grant funds that may have been compromised by wrongdoing; and
(iv) place the Global Fund in the best position to recover funds, and take remedial and preventive action, by identifying where and how the misused funds have been spent.

The OIG conducts administrative, not criminal, investigations. It is recipients’ responsibility to demonstrate that their use of grant funds complies with grant agreements. OIG findings are based on facts and related analysis, which may include drawing reasonable inferences. Findings are established by a preponderance of evidence. All available information, inculpatory or exculpatory, is considered by the OIG.\(^{13}\) As an administrative body, the OIG has no law enforcement powers. It cannot issue subpoenas or initiate criminal prosecutions. As a result, its ability to obtain information is limited to the access rights it has under the contracts the Global Fund enters into with its recipients, and on the willingness of witnesses and other interested parties to voluntarily provide information.

The OIG bases its investigations on the contractual commitments undertaken by recipients and suppliers. Principal Recipients are contractually liable to the Global Fund for the use of all grant funds, including those disbursed to Sub-recipients and paid to suppliers. The Global Fund’s Code of Conduct for Suppliers\(^{14}\) and Code of Conduct for Recipients provide additional principles, which recipients and suppliers must respect. The Global Fund Guidelines for Grant Budgeting define compliant expenditures as those that have been incurred in compliance with the terms of the relevant grant agreement (or have otherwise been pre-approved in writing by the Global Fund) and have been validated by the Global Fund Secretariat and/or its assurance providers based on documentary evidence.

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Who we investigate: The OIG investigates Principal Recipients and Sub-recipients, Country Coordinating Mechanisms and Local Fund Agents, as well as suppliers and service providers. Secretariat activities linked to the use of funds are also within the scope of the OIG’s work. While the OIG does not typically have a direct relationship with the Secretariat’s or recipients’ suppliers, its investigations encompass their activities regarding the provision of goods and services. To fulfil its mandate, the OIG needs the full cooperation of these suppliers to access documents and officials.

Sanctions when prohibited practices are identified: When an investigation identifies prohibited practices, the Global Fund has the right to seek the refund of grant funds compromised by the related contractual breach. The OIG has a fact-finding role and does not determine how the Global Fund will enforce its rights. Nor does it make judicial decisions or issue sanctions. The Secretariat determines what management actions to take or contractual remedies to seek in response to the investigation findings.

However, the investigation will quantify the extent of any non-compliant expenditures, including amounts the OIG proposes as recoverable. This proposed figure is based on:

(i) amounts paid for which there is no reasonable assurance that goods or services were delivered (unsupported expenses, fraudulent expenses, or otherwise irregular expenses without assurance of delivery);
(ii) amounts paid over and above comparable market prices for such goods or services;
(iii) amounts incurred outside of the scope of the grant, for goods or services not included in the approved work plans and budgets or for expenditures in excess of approved budgets.

How the Global Fund prevents recurrence of wrongdoing: Following an investigation, the OIG and the Secretariat agree on management actions that will mitigate the risks that prohibited practices pose to the Global Fund and its recipients’ activities. The OIG may make referrals to national authorities for criminal prosecutions or other violations of national laws and support such authorities as necessary throughout the process, as appropriate.