



Investigation Report

Proactive Investigation of Procurements of Non-Compliant HIV Rapid Diagnostic Testing Kits

GF-OIG-18-010
31 May 2018
Geneva, Switzerland

What is the Office of the Inspector General?

The Office of the Inspector General (OIG) safeguards the assets, investments, reputation and sustainability of the Global Fund by ensuring that it takes the right action to end the epidemics of AIDS, tuberculosis and malaria. Through audits, investigations and advisory work, it promotes good practice, reduces risk and reports fully and transparently on abuse.

Established in 2005, the OIG is an independent yet integral part of the Global Fund. It is accountable to the Board through its Audit and Finance Committee and serves the interests of all Global Fund stakeholders. Its work conforms to the International Standards for the Professional Practice of Internal Auditing and the Uniform Guidelines for Investigations of the Conference of International Investigators.

Contact us

The Global Fund believes that every dollar counts and has zero tolerance for fraud, corruption and waste that prevent resources from reaching the people who need them. If you suspect irregularities or wrongdoing in the programs financed by the Global Fund, you should report to the OIG using the contact details below. The following are some examples of wrongdoing that you should report: stealing money or medicine, using Global Fund money or other assets for personal use, fake invoicing, staging of fake training events, counterfeiting drugs, irregularities in tender processes, bribery and kickbacks, conflicts of interest, human rights violations...

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Audit Report

OIG audits look at systems and processes, both at the Global Fund and in country, to identify the risks that could compromise the organization's mission to end the three epidemics. The OIG generally audits three main areas: risk management, governance and oversight. Overall, the objective of the audit is to improve the effectiveness of the Global Fund to ensure that it has the greatest impact using the funds with which it is entrusted.

Advisory Report

OIG advisory reports aim to further the Global Fund's mission and objectives through value-added engagements, using the professional skills of the OIG's auditors and investigators. The Global Fund Board, committees or Secretariat may request a specific OIG advisory engagement at any time. The report can be published at the discretion of the Inspector General in consultation with the stakeholder who made the request.

Investigations Report

OIG investigations examine either allegations received of actual wrongdoing or follow up on intelligence of fraud or abuse that could compromise the Global Fund's mission to end the three epidemics. The OIG conducts administrative, not criminal, investigations. Its findings are based on facts and related analysis, which may include drawing reasonable inferences based upon established facts.

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1. Executive Summary

1.1. Summary paragraph

This proactive investigation reviewed purchases of suspected non-compliant HIV rapid diagnostic test (RDT) kits in eight countries to determine whether wrong-doing had played a role. Whilst no evidence of wrongdoing was found, four Principal Recipients in three countries were confirmed to have bought HIV RDT kits valued at US\$230,268 that were non-compliant. In this instance, the procurements did not result in a public health risk. However, Global Fund processes had not detected some of the non-compliant purchases and had erroneously verified some product information. Consequently, some components of the Global Fund's monitoring and verification of health product purchases by recipients needed strengthening. In response, the Secretariat added clarifications to the LFA guidelines to ensure that similar verification errors do not reoccur and it has agreed to revisit and clarify its quality assurance mandate for all health products. These steps will help to ensure that recipients purchase health products that are good quality, safe, appropriate and affordable.

1.2. Main OIG Findings

Principal Recipients are required by the terms of their grant agreements to enter purchases of certain key health products into the Price Quality Reporting tool (PQR). PQR is a web-based system, set up by the Global Fund, which helps it to monitor health product purchases by Principal Recipients.

Global Fund LFAs verify the accuracy of the data entered into PQR by Principal Recipients. The Global Fund Quality Assurance Team reviews PQR periodically to ensure that Principal Recipients are purchasing key health products that comply with the Global Fund's policies. The Quality Assurance Team conducted quarterly reviews of PQR until the end of 2015.

Four Principal Recipients in three countries, Georgia, South Africa and Uzbekistan, bought non-compliant RDT kits totaling US\$230,268. The Quality Assurance Team quarterly reviews identified the non-compliant purchases by the Principal Recipients in Georgia and South Africa. However, the Quality Assurance Team did not identify the non-compliant purchases in Uzbekistan.

PQR data, verified by the LFAs, for five other countries also indicated potential non-compliant purchases totaling US\$2,493,642. However, the data was erroneous and in some cases the uploaded documentation did not provide sufficient information to identify the correct product. LFA guidance did not emphasize sufficiently the importance of ensuring that the Principal Recipient accurately enters the full product description (including product code, as relevant) into PQR.

1.3. Actions Already Taken

As a result of the OIG investigation, certain entries in PQR have been corrected. The Secretariat has also issued an updated version of the LFA Guide for PQR verification emphasizing the need to verify product codes against supporting documentation.

1.4. Summary of Agreed Management Actions

The Secretariat will clarify its quality assurance mandate, including the necessary activities, roles and responsibilities.

2. Context

2.1. Proactive Investigations

This is a report of a proactive investigation. The goal of a proactive investigation is to identify wrongdoing as early as possible. A proactive investigation is intelligence-led and does not rely on allegations from third parties or whistle-blowers. By identifying signs that point to potential wrongdoing as early as possible, the OIG aims to safeguard the Global Fund's investments to end the epidemics of AIDS, tuberculosis and malaria. This also helps develop best practices and promote organizational learning. The OIG publishes the results of all its proactive investigations in the interests of transparency and accountability.

2.2. Procurement and Supply Management of Health Products

Between 2014 and 2016, the Global Fund partnership invested more than US\$10 billion to support countries fighting AIDS, TB and malaria. It invested about half of that amount in the procurement and management of health products.

The Global Fund requires its grant recipients to procure health products that comply with applicable national guidelines and/or World Health Organization (WHO) guidance. The WHO prequalification process provides assurance that products are of good quality, safe, appropriate and affordable. 'The Guide to Global Fund Policies on Procurement and Supply Management of Health Products' outlines the policies and principles that govern the procurement and supply management of health products financed by the Global Fund. All grant agreements incorporate the provisions of the guide.

The Global Fund approves the list of health products that the grant recipient intends to purchase with grant funds. This happens at the grant-making stage prior to implementation. The recipient must obtain Global Fund approval for any changes to the prior agreed list during implementation.

Reliable HIV RDT kits are key to ensuring that people know their HIV status and, if they are HIV positive, receive treatment. This is part of the 2020 UNAIDS goal known as 90-90-90; 90% of all people living with HIV will know their HIV status, 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy, and 90% of all people receiving antiretroviral therapy will have viral suppression.

2.3. Price Quality Reporting System

In accordance with their grant agreements, Principal Recipients of Global Fund grants have to report grant-funded purchases of key pharmaceutical and health products into the online PQR system. Key pharmaceutical and health products include antiretrovirals, anti-TB medicines, anti-malarial medicines, bed nets, condoms and rapid diagnostic tests for HIV and malaria. For 2016, Principal Recipients and Procurement Agents entered data into PQR for 105 different products valued at US\$848,822,470.

The LFA verifies the accuracy of implementers' entries in PQR during its Progress Update/Disbursement Request reviews. The LFA is not requested to verify if the purchased product is compliant with Global Fund Health policies during the verification process related to the Progress Updates. However, Global Fund Country Teams can ask the LFA to verify compliance through other LFA services, such as Quality Monitoring Activities for Pharmaceuticals. To assist the LFA in conducting Progress Update verifications of PQR, the Global Fund provides guidance in a document available on the Global Fund website called "An LFA's Guide to the PQR".

PQR allows for monitoring of purchases with the Global Fund's Quality Assurance Policy. The Global Fund can identify non-compliance, for enforcement purposes, through a review of PQR data on a quarterly basis. However, in the case of RDT kits, PQR reviews are a complex process due to the lack of functionality within the system to identify a product's regulatory status.

3. The Investigation at a Glance

3.1. Genesis and Scope of the Investigation

In April 2017, the OIG opened this proactive investigation into potentially non-compliant purchases of HIV RDT kits by Principal Recipients. It was initiated based on information obtained during previous OIG investigation work relating to similar issues.

The investigation reviewed PQR data for HIV RDT and Enzyme Immunoassay (EIA) kits bought between 1 January 2014 and 30 April 2017. It focused on potential purchases of non-compliant products in eight countries (Ethiopia, Georgia, Haiti, Indonesia, Paraguay, South Africa, Uruguay, and Uzbekistan) manufactured by InTec Products Inc. (product codes ITP02006-TC40/ITP02006 and ITP02002-TC40/ITP02002) and a diagnostic product manufactured by Shanghai Kehua Bioengineering Co. Ltd. (product code K-T-10).

3.2. Type of Findings Identified

■	Coercion
■	Collusion
■	Corruption
■	Fraud
■	Human Rights Issues
■	Non-Compliance with Grant Agreement
■	Product Issues

3.3. Non-Compliant Expenditure

US\$230,268: The OIG found that four Principal Recipients in three countries, Georgia, Uzbekistan and South Africa, purchased the non-compliant RDT kits, ITP02006 and ITP02002, in violation of their grant agreements.

3.4. Proposed Recoverable Amount

None: Although the OIG found instances of non-compliant purchases of RDT kits, it does not recommend recovery as Global Fund Country Teams implemented corrective measures in line with their operational policy guidance.¹

¹ “Implementing the Quality Assurance Polices for Pharmaceutical, Diagnostic and Other Health Products” paragraphs 20-23

4. Findings

4.1. Purchases of non-compliant RDT kits in Georgia, South Africa and Uzbekistan

Four Principal Recipients in three countries, Georgia, Uzbekistan and South Africa, purchased non-compliant RDT kits in violation of their grant agreements. However, no evidence of collusion or fraud was found between the Principal Recipients and their suppliers. The total value of these non-compliant purchases was US\$230,268.

Although the countries purchased non-compliant products, there was no evidence that this resulted in a public health issue.

Georgia

A Principal Recipient made one procurement of 33,450 ITPO2006, HIV RDT kits costing US\$21,944 in October 2014. The LFA verified the PQR entry for accuracy and completeness on 22 September 2015. Following its quarterly PQR review, in March 2016, the Quality Assurance Team contacted the Georgia Country Team, informing them that the Principal Recipient had bought non-compliant RDT kits.

The Principal Recipient told the Country Team that they had purchased ITPO2006 because the Georgian Ministry of Health and Social Affairs certified the product; the AIDS Center in Georgia had tested the product and found no problems with it; and the product was included in the PQR product list, which allowed the Principal Recipient to make the entry.

Nevertheless, on 20 April 2016, in accordance with its Operational Policy Note, the Country Team issued a warning letter advising the Principal Recipient to stop purchasing ITPO2006 or the Global Fund would seek reimbursement. The Principal Recipient has since stopped the purchase of ITPO2006.

South Africa

Between 2015 and 2016, on 12 occasions, two Principal Recipients locally procured 435,525 non-compliant RDT kits ITPO2002 valued at US\$195,476.

From April 2014 to March 2017, the South African government contracted with a supplier to purchase ITPO2002 RDT kits based on the nationally approved algorithm. At the time of contracting, these RDT kits were on the WHO “List of HIV diagnostics eligible for tender for procurement”. However, in September 2014 WHO removed the product from the list at the request of the manufacturer.² However, the RDT kits were retained on the nationally approved algorithm and the two Principal Recipients continued to purchase these kits until September 2016.

The LFA verified the relevant PQR entries made by one Principal Recipient between February and June 2016. For the other Principal Recipient, the LFA verified all but one of the PQR entries in 2015 and 2016. For the RDT kits received on 16 September 2016, based on information from the Country Team, the LFA verified their compliance status and noted in PQR that the kits were non-compliant. The LFA recommended that the Principal Recipient to stop buying this product using funds from the Global Fund grant.

On 10 July 2017, the South Africa Country Team advised the second Principal Recipient that, under the procurement plan for the Grant Confirmation signed 14 April 2015, the RDT kits it had bought

² The Global Fund removed the product from its list in November 2014

were no longer approved. Therefore, the purchase made in September 2016 for US\$ 5,505.95 was ineligible. In response, the second Principal Recipient agreed to reimburse this amount.

Uzbekistan

In May 2014 and March 2015, a Principal Recipient procured 36,280 non-compliant RDT kits, ITPO2006, valued at US\$12,848.

The LFA verified the PQR entries for the May 2014 consignment on 14 August 2014, and for the March 2015 consignment on 19 October 2015. The OIG's review of the documents uploaded into PQR by the Principal Recipient for the two consignments established that the RDT kits were non-compliant.

The Principal Recipient said it had purchased ITPO2006 in 2014 and 2015 and the LFA had verified the two purchases. Neither the LFA nor the Secretariat had raised any issues at the time.

In addition, the Principal Recipient said that during the period in question the manufacturer of the product had long-term agreements in place with UN agencies operating in the country. The OIG's review established, however, that the manufacturer sells both compliant and non-compliant products. The grant closed on 31 December 2016 and the Principal Recipient is no longer implementing Global Fund grants in Uzbekistan.

4.2. Other potential non-compliant purchases of RDT kits

In the remaining five countries that had potentially bought non-compliant RDTs, the Principal Recipients had entered incorrect information into PQR. Consequently, purchases totaling US\$ 2,493,642 were in fact compliant. The LFA had verified most of the erroneous entries, although in some cases the Principal Recipient had not uploaded sufficient documents to allow the LFA to determine which type of product had been bought.

The OIG found two erroneous entries in PQR for products manufactured by Shanghai Kehua Bio-engineering Co. KH-R-2 is the Global Fund-approved RDT kit. However, Principal Recipients in Ethiopia and Haiti entered the product code KH-T-10, a non-compliant product.

In November 2015, a Principal Recipient in Ethiopia entered into PQR the purchase of 97,436 diagnostic kits KH-T-10 for US\$2,433,650. The LFA verified the entry in February 2016 based on supporting documentation that contained only the product description and not the product code. A Quality Assurance Team quarterly review of PQR identified that the Principal Recipient in Ethiopia entered the non-compliant product KH-T-10. The Quality Assurance Team subsequently verified through the Country Team that the Principal Recipient had purchased KH-R-2. The Principal Recipient has not corrected the PQR entry.

In June and September 2016, a Principal Recipient in Haiti entered into PQR the purchase of KH-T-10 for \$6,823. In this case, the LFA was unable to verify the product because the grant had ended, the Principal Recipient's offices had closed, and key documents were not available. The OIG contacted UN procurement, through the UN Office of Audit and Investigations, who confirmed that the Principal Recipient had purchased KH-R-02.

The OIG found an erroneous entry in PQR made in March 2014 for a procurement conducted through the Global Fund Pooled Procurement Mechanism for an Indonesian Principal Recipient. The Procurement Agent recorded in PQR that it had purchased ITPO2006, but it had in fact bought ITPO2002, which was compliant at the time. In 2017, during the course of the investigation, the OIG contacted the Global Fund Sourcing Team about the error and shortly after, the Procurement Agent corrected the entry. The LFA had verified the original entry in 2015 and had not identified the error, but the invoice did not provide the manufacturer's product code.

On two occasions in 2016, a Principal Recipient in Paraguay entered into PQR the purchase of non-compliant RDT kits, ITPO2006. At the time of the investigation, the LFA had not yet reviewed the entry. The Quality Assurance Team identified the error in March 2017, but could not confirm the type of product purchased from the uploaded invoices and alerted the Paraguay Country Team. The Paraguay Country Team confirmed the products purchased were not InTec RDT kits, but RDT kits from two other manufacturers that were compliant. The Principal Recipient corrected the PQR entry.

On two occasions in 2014, a Principal Recipient in Uruguay had entered into PQR the purchase of the non-compliant RDT kit ITPO2006. However, the Principal Recipient had in fact purchased ITPO2002, which at the time was compliant. The LFA verified these purchases, although the invoices did not stipulate which InTec product the Principal Recipient purchased.

A Principal Recipient in Uzbekistan entered information into PQR in September 2016 (for a product ordered in December 2015) that was incorrect. The PQR entry indicated that the Principal Recipient purchased ITPO2002, which was non-compliant at the time of ordering. However, the uploaded invoice stated that the Principal Recipient purchased the newly approved InTec product ITPO2121.

4.3. PQR verification lapses by Quality Assurance Team and LFA

Quality Assurance Team

The Global Fund's Operational Policy Note "Implementing the Quality Assurance Policies for Pharmaceutical Diagnostics and Other Health Products", advises that the objectives of Quality Assurance policies are to ensure that grant recipients procure quality-assured health products and obtain value for money. The note also states that adherence to quality assurance policies play a critical role in mitigating risks related to poor quality and substandard products.

From approximately 2012 to December 2015 The Quality Assurance Team performed quarterly reviews of PQR. The team employed a consultant who performed this task. The Quality Assurance Team did not carry out any quality assurance reviews of PQR in 2016. In 2017, it only reviewed entries for pharmaceutical products and PQR data on an ad-hoc basis following information or query received from various internal and external partners.

The Quality Assurance Team quarterly reviews identified the non-compliant purchase by the Principal Recipient in Georgia and South Africa. However, the team did not identify the non-compliant purchases in Uzbekistan.

The team said it has insufficient staff to undertake quarterly reviews of PQR because the reviews are time-consuming, especially in the case of RDT kits. This is due to the lack of functionality within PQR to identify a product's regulatory status.

Agreed Management Action 1

The Secretariat will clarify the Secretariat's Quality Assurance mandate, including the necessary activities, roles and responsibilities.

Owner: FISA

Due date: 30 June 2019

Category: Health Services and Product Risk

LFA

The LFA relies on the Global Fund guide “An LFA’s Guide to the PQR” to verify PQR entries. This document outlines the LFA’s scope of work, the role of PQR and examples of common data entry errors. The LFA is required to perform ‘PQR verification’ during the Progress Update/Disbursement Request.

The LFA is not responsible for ensuring that health products purchased by Global Fund implementers are compliant with Global Fund Health Policies. Instead, the LFA is required to verify the accuracy of the PQR data entries to supporting documentation and to contact the Principal Recipient if there is insufficient documentation for verification.

However, this investigation found that the LFA had verified most of the PQR entries relating to the potentially non-compliant purchases, although in most cases the Principal Recipient had uploaded insufficient documents for the LFA to determine the type of product purchased.

The investigation also found that the LFA guidance does not emphasize sufficiently the importance of ensuring that the Principal Recipient accurately enters the product description into PQR. For example, it does not refer to checking product codes in this verification process.

For example, InTec manufactures at least nine differently coded HIV RDT kits. Currently, only one product code is compliant, but three are available for the Principal Recipient to select from in a drop down box in PQR. In the event that the invoice only contains a description, the LFA should contact the Principal Recipient to confirm the product code.

Based on the OIG’s findings, the Secretariat has updated the LFA Guide to PQR. Subsequent to the investigation, the LFA is now required to check product codes against the supporting documents. If any information required by the LFA is not included in the supporting documents provided by the Principal Recipient, the LFA should request the required documentation before it marks the product as verified in the PQR.

5. Table of Agreed Actions

Agreed Management Actions	Target date	Owner	Category
1. The Secretariat will clarify the Secretariat's Quality Assurance mandate, including the necessary activities, roles and responsibilities.	30 June 2019	FISA	Health Services and Product Risk

Annex A: 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, limits impact and reduces the trust, which 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 Secretariat of the Global Fund, by recipients of grants funds, or their respective suppliers. OIG investigations identify instances of wrongdoing, such as fraud, corruption and other types of non-compliance with the grant agreements. The Global Fund Policy to Combat Fraud and Corruption³ generally outlines the prohibited practices, which will result in investigation findings.

OIG investigations aim to:

- (i) identify the specific 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 preventative action, by identifying where and how the misused funds have been used.

OIG conducts administrative, not criminal, investigations. It is the recipients’ responsibility to demonstrate their compliance with the grant agreement in their use of grant funds. Its 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.⁴ 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 and its recipients enter into, 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 Suppliers⁵ and Code of Conduct for Recipients provide additional principles, which recipients and suppliers must respect. Global Fund Guidelines for Budgeting generally define how expenditures must be approved and evidenced to be recognized as compliant with the terms of the grant agreements.

Who we investigate: Principal Recipients and Sub-recipients, Country Coordinating Mechanisms and Local Fund Agents, as well as suppliers and service providers. Secretariat activities linked to the

³ (16.11.2017) Available at https://www.theglobalfund.org/media/6960/core_combatfraudcorruption_policy_en.pdf

⁴ These principles comply with the Uniform Guidelines for Investigations, Conference of International Investigators, 06.2009; available at: http://www.conf-int-investigators.org/?page_id=13, accessed 1.12.2017.

⁵ Global Fund Code of Conduct for Suppliers (15.12.2009), § 17-18, available at:

https://www.theglobalfund.org/media/3275/corporate_codeofconductforsuppliers_policy_en.pdf, and the Code of Conduct for Recipients of Global Fund Resources (16.07.2012), §1.1 and 2.3, available at:

https://www.theglobalfund.org/media/6011/corporate_codeofconductforrecipients_policy_en.pdf. Note: Grants are typically subject to either the Global Fund’s Standard Terms and Conditions of the Program Grant Agreement, or to the Grant Regulations (2014), which incorporate the Code of Conduct for Recipients and mandate use of the Code of Conduct for Suppliers. Terms may vary however in certain grant agreements.

use of funds are also within the scope of work of the OIG.⁶ While the OIG does not typically have a direct relationship with the Secretariat's or with recipient suppliers, its scope⁷ encompasses their activities regarding the provision of goods and services. To fulfill its mandate, the OIG needs the full cooperation of these suppliers to access documents and officials.⁸

Sanctions when prohibited practices are identified: When the 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.⁹ The Secretariat determines what management actions or contractual remedies to take, 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, for which there is no reasonable assurance about delivery of goods or services (unsupported expenses, fraudulent expenses, or otherwise irregular expenses without assurance of delivery);
- (ii) amounts which constitute over pricing between the price paid and comparable market price for such goods or services; or
- (iii) amounts incurred outside of the scope of the grant, for good and services not included in the approved work plans and budgets or expenditures over approved budgets.

How the Global Fund prevents recurrence of fraud: Following an investigation, the OIG and Secretariat agree on management actions that will mitigate the risks of prohibited practices 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 supports such authorities as necessary throughout the process, as appropriate.

⁶ Charter of the Office of the Inspector General (19.03.2013), § 2, 9.5, 9.6, 9.7 and 9.9 available at: https://www.theglobalfund.org/media/3026/oig_officeofinspectorgeneral_charter_en.pdf

⁷ Charter of the Office of the Inspector General § 2, and 17.

⁸ Global Fund Code of Conduct for Suppliers, § 16-19

⁹ Charter of the Office of the Inspector General § 8.1