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OIG investigation reveals deficiencies in Global Fund processes for procurement of HIV rapid test kits in eight countries

A proactive investigation undertaken by the Office of the Inspector General (OIG) has identified some deficiencies in the Global Fund's processes for procuring HIV rapid diagnostic test (RDT) kits. A [report](#) on the investigation was released on 31 May 2018.

The goal of a proactive investigation is to identify possible wrongdoing as early as possible. Proactive investigations do not rely on allegations from third parties or whistle-blowers. This particular investigation was initiated based on information obtained during previous OIG investigations into related matters.

A major impetus for this investigation was the fact that of the more than \$10 billion invested by the Global Fund between 2014 and 2016, about half of that amount was spent procuring and managing health products.

The OIG reviewed price, quality and reporting (PQR) data for HIV RDT kits purchased between 1 January 2014 and 30 April 2017 in eight countries: Ethiopia, Georgia, Haiti, Indonesia, Paraguay, South Africa, Uruguay and Uzbekistan.

The investigation found that four principal recipients (PRs) in three countries — Georgia, South Africa and Uzbekistan — purchased HIV RDT test kits valued at \$230,268 that were non-compliant because they were not on the World Health Organization's list of pre-qualified products and were not approved by the Global Fund.

The report on the investigation does not identify the PRs involved. Dougal Thomson, a spokesperson for the OIG, told Aidspan that this was intentional. "The work we did in Georgia, South Africa and Uzbekistan

did not uncover ‘intentional wrongdoing’ and therefore the findings are not subject to the same due process, nor are they subject to mandatory public disclosure under our disclosure policy,” Thomson said. “The focus of this report is not the PRs, but [rather on] the Global Fund’s quality assurance processes.”

The Fund requires that when grant recipients purchase health products, they must comply with applicable national guidelines and/or guidance from the World Health Organization (WHO) — as well as the Fund’s own [Guide to Global Fund Policies on Procurement and Supply Management of Health Products](#). The guide states that grant implementers must obtain the approval of the Global Fund for all health products they intend to purchase. All grant agreements incorporate the provisions of the guide.

The OIG said that no evidence of wrongdoing (such as collusion or fraud) was found; and that the non-compliant procurements did not result in a public health risk. However, Global Fund processes failed to detect some of the non-compliant purchases and erroneously verified some product information.

Under the terms of their grant agreements, PRs are required to record purchases of certain health products into the PQR system. (For 2016, for example, PRs and procurement agents entered data into the PQR for 105 products valued at \$848.8 million.) Local fund agents (LFAs) are required to verify the accuracy of the data.

In addition, the Global Fund’s Quality Assurance Team reviews the PQR data periodically. Until the end of 2015, the OIG said, the team conducted quarterly reviews of the data. However, in 2016, no quarterly reviews of non-pharmaceutical products were carried out. And in 2017, the team only reviewed entries for RDT kits and other non-pharmaceutical products on an ad-hoc basis when it received specific information or a query. The team said that although it was able to conduct quarterly reviews of the data for pharmaceutical products, it had insufficient staff to undertake these reviews for non-pharmaceutical products. According to the OIG, the team explained that PQR reviews are a complex process, particularly in the case of RDT kits, because there is a lack of functionality within the system to identify the kits’ regulatory status.

Non-compliant purchases

The Quality Assurance Team identified the non-compliant purchases made by PRs in Georgia and South Africa. However, the team did not identify the non-compliant purchases in Uzbekistan. Below, we provide a summary of the OIG’s findings in each of these three countries.

Georgia

In October 2014, the OIG said, the PR purchased 33,450 units of a particular HIV RDT kit called ITP02006, valued at \$21,944. In September 2015, the LFA verified the PQR entry for accuracy and completeness. During a review of procurement data entered in the PQR database in 2015, the Quality Assurance Team identified that the kits were non-compliant, and it informed the country team.

The PR told the country team that it had purchased ITP02006 because the Georgian Ministry of Health and Social Affairs had certified the kits; the AIDS Center in Georgia had tested the kits and found no problems with them; and the kits were included on the PQR product list.

Nevertheless, the OIG said, in April 2016, the country team issued a warning letter advising the PR to stop purchasing ITP02006. The PR has complied.

South Africa

The OIG said that between 2015 and 2016, on 12 occasions, two PRs locally procured 435,525 ITP02002 RDT kits valued at \$195,476. The South African government had contracted with a supplier to purchase

ITP02002 RDT kits based on a nationally approved algorithm. Initially, the OIG said, these RDT kits were on the WHO's list of HIV diagnostics eligible for procurement. However, in September 2014, the WHO removed the product from the list at the request of the manufacturer. Nevertheless, the RDT kits were retained in the national algorithm and the two PRs continued to purchase the kits until September 2016.

Uzbekistan

In two separate orders, in May 2014 and March 2015, the Uzbekistan PR procured 36,280 RDT kits valued at \$12,848. The OIG's review of the documents uploaded into the PQR database by the PR established that the RDT kits were non-compliant.

The LFA had verified the PQR entries for both consignments. According to the OIG, the PR said that neither the LFA nor the Secretariat raised any issues at the time. In addition, the PR said that during the period in question, the manufacturer of the RDT kits had long-term agreements in place with U.N. agencies operating in the country. The OIG's investigation established, however, that the manufacturer sells both compliant and non-compliant products to the U.N. agencies.

The report on the investigation revealed that the grant closed on 31 December 2016 and that the PR is no longer implementing Global Fund grants in Uzbekistan.

Other countries

In the remaining five countries, the OIG's review identified \$2.5 million in potentially non-compliant procurements. However, in all instances, the data entered in the PQR database by the PRs was erroneous, the OIG said. In some cases, the data did not provide sufficient information to identify the correct product.

One transaction by a PR in Ethiopia accounted for most of the \$2.5 million. In November 2015, the PR entered into PQR database the purchase of 97,436 diagnostic kits called KH-T-10, which had a value of \$2,433,650. The LFA verified the entry based on supporting documentation that contained only the product description and not the product code. A Quality Assurance Team review identified the purchase as non-compliant. However, the team subsequently verified through the country team that the PR had actually purchased a different kit, KH-R-2, which was on the WHO list of pre-qualified products.

The investigation found that the Global Fund's LFA guidance does not sufficiently emphasize the importance of ensuring that PRs accurately enter the product description into the PQR system.

Actions taken

As a result of the investigation, the Secretariat has updated its guidelines for LFAs ([A Local Fund Agent's Guide to Price and Quality Reporting](#)) and has agreed to clarify its quality assurance mandate, including activities, roles and responsibilities. "These steps will help to ensure that recipients purchase health products that are good quality, safe, appropriate and affordable," the OIG said.

In addition, some entries in the PQR database have been corrected.

The OIG did not recommend that the Global Fund try to recover the amounts involved in the purchase of non-compliant RDT kits because, it said, the country teams have already implemented corrective measures.

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