

U.S. President's Malaria Initiative (PMI) Approach and Steps to Counter Theft and Diversion of Medicines

“We are working with national governments, medical stores and local institutions to strengthen oversight to ensure the safe delivery of drugs. This includes funding and technical assistance to strengthen all areas of the pharmaceutical supply chain.”

“The U.S. Government strongly condemns the theft and illegal diversion of medicines that are intended to cure malaria, particularly in the most vulnerable populations in Sub-Saharan Africa – pregnant women and children under five years old.”

“And we are using all channels including, diplomatic, public health, and refer information to law enforcement, to counter the theft and illegal diversion of malaria drugs.”

R.T. Ziemer,
Rear Admiral U.S. Navy (RET)
U.S. Malaria Coordinator

Illegal Diversion

Since 2010, media reports have periodically highlighted the transcontinental diversion of donor financed malaria commodities, including President's Malaria Initiative (PMI), antimalarial medicines in Africa. PMI has periodically addressed this issue in its annual reports (http://www.pmi.gov/resources/reports/pmi_annual_report12.pdf, p.29). Illegal diversion occurs when a genuine pharmaceutical product approved and intended for use in one country is illegally intercepted and sold in another. Diversion affects not only malaria, but also impacts many different high-value product markets and countries.

Various factors contribute to the theft of medicines, including weak regulatory and enforcement capacity, corruption, and the lack of financial, technical and other resources in developing countries to ensure the security of drug supply chains. Public sector supply chains in Africa are particularly vulnerable to theft or loss, due to weaker systems of inventory, internal controls, management information systems, and transportation.

USG-funded artemisinin-based combination therapies (ACTs), the WHO-recommended first line treatment for uncomplicated malaria, form one of the major cornerstones of the President's Malaria Initiative (PMI) malaria control efforts. The consequence for a malaria-endemic population of not having prompt effective treatments by ACTs would be immediate increases in child mortality.

PMI leadership takes the theft of medicines and other commodities very seriously and have developed a comprehensive strategy to address the issue. In approaching the theft issue, PMI's goal has been to “do no harm” by ensuring that ACTs and other malaria commodities continue to reach the intended beneficiaries, while taking action to ensure accountability and integrity in the supply chain and working with national governments to address any problems that are identified.

PMI has taken and will continue to take the following steps to prevent diversion and theft of these life-saving drugs in the medicine supply chain:

- Working with national governments and the regulatory authorities responsible for protecting the supply chains, such as Central Medical Stores and Ministries of Health, to improve vigilance and oversight of drug distribution and mitigate the theft and diversion of essential medicines;
- Providing technical and financial resources to strengthen supply chains and track USAID-financed malaria commodities. Measures include installation of security systems, central-level stock tracking, periodic physical inventories, and rapid health facility surveys to monitor U.S. Government-financed antimalarial commodities. These steps have improved transparency in these systems and have been responsible for detecting loss and diversion of commodities and serve as an early-detection system at national and sub-national levels;
- Referring information to the USAID Office of Inspector General, as needed;
- Exploring with manufacturers the possibility of adding special markings or tags for ACTs and long-lasting insecticide-treated bed nets (LLINs) that would facilitate the tracking of U.S. Government products through local supply chains and assist local law enforcement efforts;
- Urging accountability and tighter controls within national supply chains through diplomatic channels with the State Department;
- Review product distribution channels at the country level; and
- Engaging and coordinating with a range of multilateral and bilateral partners, including the Global Fund, to prevent the loss or theft of medicines and develop transparent, coordinated, country-level action plans to significantly reduce the diversion of medicines.

Additional steps include:

- PMI has piloted tools to assess host governments' internal controls-including financial aspects when warranted-in managing the supply chain of PMI-funded commodities to guard against fraud or corruption. These assessments have identified specific vulnerabilities in the systems and provided recommendations for corrective actions, such as implementing additional security or stronger inventory management.
- Where there has been credible evidence of theft, corruption or fraud, the U.S. government has taken strong action to safeguard PMI-funded commodities and their intended recipients. Actions have included ensuring the movement of PMI-funded commodities through separate non-governmental parallel systems with greater internal controls. At the same time, the U.S. government pursues high-level diplomacy with recipient

governments to ensure that critical reforms are undertaken prior to returning high-value malaria commodities to the national government system.

PMI has expended considerable effort working with recipient countries and other donors to track and monitor PMI-financed commodities at lower levels of country-owned supply chains, and has increased investments in identifying and correcting vulnerabilities in the system. In addition, the USAID's Office of the Inspector General/Audit incorporates PMI's provision of commodities to national governments in their routine audit scopes. As a result, PMI has documented other instances of theft involving malaria commodities financed by PMI and other donors in several African countries.

Public sector supply chains are still weak in many African countries and public health facilities are often stocked out of essential medicines, including antimalarial medicines. In many countries, patients will often first turn to the private sector¹ for fever treatment. This leads to a high "black market" value for malaria treatments in the private sector in several African countries.

From 2007 to the present, USAID/PMI has procured and distributed nearly \$500 million in long-lasting insecticide-treated nets (LLINs), antimalarial medicines, and rapid diagnostic tests. The vast majority of these commodities reach their intended beneficiaries and PMI has taken a number of additional steps to mitigate the risks of diversion. The dollar value of diverted commodities is unknown.

2.2. USG-Donated Medicines from Manufacturer to Country

The overall supply chain for distributing PMI donated medicines to recipient countries can be broken down into two major segments. The first segment begins at the point of purchase and includes the pick-up of goods and all related logistics to transport the commodities from the manufacturer to delivery to the recipient country consignee. This segment is controlled through USAID-contracted procurement agents. The second segment is the local country supply chain, which delivers products from the point of consignment to districts governments, designated health facilities or other service delivery points. This segment is normally beyond U.S. government direct control and is typically operated and managed by the recipient government. The U.S. government supports this portion of the supply chain through supply chain technical assistance and funding.

PMI funds the public-sector procurement of WHO-recommended ACTs and long lasting insecticidal nets (LLINs) in nearly all PMI focus countries. Medicines and rapid diagnostic tests are usually transported by air to a country directly from the manufacturer due to short shelf-life issues of these commodities. LLINs are usually transported by sea from Asia² and then overland by trucks or sometimes rail. All products are insured from the point of pick up, while in transit, and until final consignment at the country level. All PMI-financed products, including LLINs, adhere to stringent quality assurance standards and testing protocols to ensure quality.

¹ Private sector definition typically includes private clinics, NGOs, pharmacies, and informal medicine vendors. In this case, the informal medicine vendors and pharmacies (licensed and unlicensed) are the primary distribution point for diverted malaria medicines. These pharmacies and medicine vendors are largely unregulated.

² PMI also procures from a company based in Tanzania.

To date, PMI has received no reports of thefts of PMI-financed commodities from the point of manufacture while in transit to the country. Minor discrepancies in delivery amounts or damage while in-transit have been resolved by re-counting commodities on arrival and reconciliation, manufacturer replacement of damaged goods, or insurance reimbursement.

2.3 Theft of PMI-Donated Medicines within Country Systems

PMI's commodity donation program provides supply chain technical assistance at the country level and works closely with national government counterparts to improve the performance and integrity of the country-owned and -managed supply chains. In 2010, USAID discovered that PMI/USAID-funded ACTs (specifically Coartem™) intended for use in public sector clinics in several East African countries were being sold in informal pharmacies and medicine vendors in West African countries.

Since 2010, PMI has found other instances of theft and transnational and transcontinental diversion of antimalarial drugs funded by USAID and other donors. Theft of LLINs has also been reported in several countries.

PMI has taken a number of steps to mitigate the risk of theft and respond when these instances are reported:

a. Supply Chain Strengthening

- On average, PMI allocates approximately 40-50% of annual country budgets to the procurement and distribution of lifesaving malaria commodities. The success of PMI in achieving reductions in malaria-related morbidity and mortality is predicated on an uninterrupted supply of high-quality commodities. Consequently, a robust supply chain system that can ensure the integrity of products as they move down the supply chain to the end user where visibility becomes weaker is paramount.
- The service delivery points for antimalarial medications and commodities are the health facility, community health workers, or the beneficiary's home (in the case of LLINs), often in remote, rural areas where oversight and systems are weak. In response to these conditions, PMI provides funding to strengthen country-level supply chain functions, such as forecasting, transportation, warehousing, and inventory management in every focus country. These activities to strengthen supply chain are coordinated and jointly funded with PEPFAR and family planning programs, where possible.
- PMI has developed additional tools to provide greater visibility and information on malaria commodities. The End-Use Verification (EUV) survey is a rapid health facility survey of commodity availability, typically implemented on a quarterly basis in most PMI countries. Monitoring the physical availability of a product for the intended user helps substantiate the integrity of the supply chain system and verifies that appropriate controls are in place.
- In addition to the EUV tool, PMI implements a central stock status monitoring tool to provide quarterly updates (monthly in some countries) on the stock levels of antimalarial drugs and related commodities. Since the report is generated only once a quarter and

data collection and collating takes several weeks, it is used primarily to avoid or address pending stock-outs on a larger scale, serving essentially as an early detection system for future commodity issues. The report is typically shared with other donors in an effort to promote transparency and to ensure that collaboratively a country's antimalarial needs are met. This report provides additional information on malaria commodities forecasting, relevant procurement data, risk of shortages, and pending Global Fund disbursements.

- As part of PMI's response to the ACT diversion problem, the USAID/Global Health Bureau developed a supply chain internal control assessment (SLICE) tool to help PMI assess internal control systems (financial and commodity) of recipient governments' supply chains that receive USG-funded medicines and diagnostics. The objective of this tool, which has been piloted in several countries, is to determine if and where there are internal control weaknesses that the USG can address to better secure our commodities, improve supply chain record keeping, and predict/prevent diversion. The assessments will help provide USAID with a basis for appropriately managing the risk in varying contexts.

b. Review of Product Distribution

- PMI has been reviewing the distribution of products at the country level through a variety of means in the public and private sectors to monitor the availability and market dynamics at various distribution points at the country level. Activities may include health facility assessments, monitoring requisition and receipt documentation, and availability/pricing in informal markets.

c. Diplomatic Engagement and Country Level Responses

- When instances of theft or transcontinental diversion have been detected, PMI has tailored its response to the specific circumstances within that country. As a first step, the USAID Office of Inspector General/Investigations is informed of all known details.
- In addition, USAID has consistently engaged the State Department at the country level and in Washington to consider diplomatic options, where sound evidence of anti-malaria drug diversion exists. In Malawi, based on substantial evidence of diversion, USAID and Department of State determined that all USG-funded commodities should be moved through a non-governmental, parallel system pending critical reforms at the government's Central Medical Stores. A similar decision was made in Angola in 2009.

4. Conclusion

The U.S. Government has taken a number of diplomatic, programmatic, and technical steps to combat the issue of the theft and misappropriation of medicines and referred information to the USAID/Inspector General/Investigations. The U.S. Government continues to work with recipient country stakeholders at all levels to improve the accountability, transparency and performance of supply chains to ensure that the integrity of our programs is maintained and the intended beneficiaries are served.

Despite these challenges, the unprecedented scale-up of malaria prevention and treatment interventions over the past 10 years in sub-Saharan Africa is having a major impact on malaria illnesses and deaths. According to the World Health Organization (WHO) 2012 *World Malaria Report*, the estimated number of global malaria deaths has fallen by more than one third—from about 985,000 in 2000 to about 660,000 in 2010. PMI continues to see strong progress—mortality rates among children under five years of age in 12 PMI focus countries with two or more nationwide household surveys that measured mortality have shown declines ranging from 16 percent (Malawi) to 50 percent (Rwanda).