

High-Level Meeting Theft and Illegal Diversion of Medicines Meeting Report

4 December 2011, Addis Ababa, Ethiopia

Background

On 4 December 2011, the Global Fund in collaboration with the Roll Back Malaria Partnership convened a high-level meeting of partners and country representatives in Addis Ababa, Ethiopia, to discuss and map out strategies to address the global issue of theft and illegal diversion of medicines. The meeting brought together Ministers of Health, Deputy Ministers of Health and senior policy makers from implementing countries and the donor community, technical partners and advocacy groups, and represented an opportunity to demonstrate the preventive steps taken by the Global Fund, countries and partners to combat illegal diversion of medicines, to review recent progress and findings, and to advocate for strengthened collaboration and scaled-up responses.

The principal objective of the meeting was to provide a forum for consideration of the following:

- i. An overview of the extent of the issue of theft of medicines globally;
- ii. Sharing of data and analysis to identify patterns in theft of medicines from Global Fund-funded programs;
- iii. Sharing of methods used and progress made to date in addressing illegal diversion by countries and partner agencies; and
- iv. “What success would look like”: policy discussion and recommendations to prevent illegal diversion of medicines.

The Global Fund utilised this forum to inform stakeholders of the scope and scale of its expanded risk management approach, and to present the findings of the Pharmaceutical and Health Product Management (PHPM) Risk Assessments carried out by Local Fund Agents (LFAs) in 20 prioritized high-risk countries, reflecting the importance placed on the prevention of theft and illegal diversion of medicines in Global Fund-supported countries. A presentation from USAID outlined mitigation strategies and measures, and analysis of the results of risk assessments, two of which were carried out in collaboration with the Global Fund, while the Global Fund Office of the Inspector General presented findings of audits and market surveys, noting trends and challenges.

The initial findings of the LFA risk assessments revealed the categories of risk most commonly encountered as well as the points in the supply chain where identified risks were most likely to be exploited. Analysis of the results of the risk assessments has demonstrated the following:

- Most commonly encountered risk categories include:
 - Chain of Custody;
 - Inventory Management;
 - Management & Oversight, and
 - Quantification and Distribution Planning.
- Storage at Central Medical Stores and peripheral facilities was identified to be the most-at-risk level in the supply chain.
- Little differentiation in risks encountered by disease category. However, artemisinin-based combination therapies (ACTs) are more commonly targeted for theft or illegal diversion than are antiretrovirals (ARVs) or medicines for opportunistic infections (OIs).

Presentations from Sierra Leone, Ethiopia, Rwanda, the Dominican Republic and Uganda outlined the issue of drug theft from the country perspective, noting challenges faced, key risks, effective mitigation strategies and lessons learned in addressing theft and illegal diversion of medicines, and setting the context for discussions on best practices in combating theft and illegal diversion at country level.

The meeting lasted one day with the afternoon reserved for high-level policy discussions and development of recommendations. Through group discussions, meeting participants considered the following critical areas in relation to the prevention and mitigation of theft and illegal diversion of medicines:

- i. Supply Chain Security;
- ii. Theft Risks – Detection and Mitigation Measures;
- iii. Law Enforcement and Investigation; and
- iv. Partnership Opportunities.

Summary of Meeting Outcomes

Participants developed the following recommendations to guide implementation of country-specific action plans and development of regional and cross-border collaborations.

Recommendations for countries/implementers:

- **Develop a coordinated country-specific response, led by the Ministry of Health:** Ensure that the development and coordination of each country action plan is led by and entrusted to the appropriate office in the Ministry of Health (MOH): Department of Pharmaceutical Service at all levels. Enlist support of donors, health development partners, private sector, civil society, regulatory authorities, anti-corruption bodies, professional councils, police, Ministry of Justice, and Ministry of Finance in defining and implementing approach.
- **Investigate regional approaches to prevent or deter cross-border trade:** Strengthen sustainable interdisciplinary/regional cooperation through the creation of specific multi-agency dedicated enforcement units (including regional bodies, Ministries of Health, customs, law-enforcement, Interpol). Share information, and develop joint response for cross-border/point of entry issues (e.g. AMFm & non-AMFm).
- **Invest in simple and scalable logistic management information system (LMIS) solutions:** Develop functional LMIS capabilities that are integrated across all levels of the supply chain. Implement very simple IT tools that can be incrementally improved, rather than complex systems that are difficult to use. Emphasize tools that have been successfully implemented in the past by other organizations. Provide training on use and expectations for data collection and reporting.
- **Clearly define operating processes, establish and enforce accountability:** Develop standard operating procedures, specifically for inventory management, chain of custody and quantification. Establish accountability by segregating duties and clearly defining process responsibility (consider system of dual-accountability). Create incentives for enforcing process compliance through a combination of disciplinary actions and rewards. Define metrics to monitor process performance, establish regular data collection, and assign responsibility for oversight and enforcement. Institute regular audits and unannounced physical inventory counts, as an additional means of detection and deterrence.
- **Consider private sector alternatives to address inadequate capacity:** Sub-contract supply chain functions (e.g. customs clearance, warehousing, transportation, procurement) when organizations are unable to meet desired

performance targets or where there is inadequate capacity or skills to perform required functions. In parallel, continue to invest in health systems strengthening activities, focusing on implementing solutions that can be sustained in the long-term.

- **Strengthen chain of custody controls:** Improve visibility of product movement through-out the supply chain by establishing regular reporting and reconciliation. Incorporate batch tracking requirements in standard operating procedures. Define minimum data collection requirements, including information on stock levels, issuances, receipts, expiry and damage. Perform regular reconciliation, and investigate major discrepancies.
- **Consider shortening the supply chain, increasing product velocity:** To the extent possible, minimize the number of transfers of product from manufacturer to end-user, while still maintaining acceptable service levels. Increase velocity of product movement, to send smaller quantities, more frequently to reduce incentives for theft, and minimize product loss in the event of theft or diversion.
- **Partner with law enforcement:** Work with law enforcement to promote advocacy and awareness of consequences of theft. Consider partnering with law enforcement to strengthen chain of custody controls. Remove barriers to prosecution, and cooperate on investigations and prosecution.
- **Prioritize preventative measures on areas with highest risk and impact:** Emphasize mitigation actions for high-value items, where a lucrative private market exists (e.g. ACTs), and where the likelihood of theft or diversion is greater. Prioritize resources to shore up the weakest areas of the supply chain (Central Medical Stores, peripheral facilities), or where the potential for theft of large quantities exists (Port of entry).

Recommendations for partners:

- **Support the development and implementation of country-specific action plans:** Provide resources and technical assistance to define actions required for successful implementation of recommendations. Through organizational partnership models, engage private sector and civil society to support governments in implementing action plans.
- **Support the development of inter-country/regional partnerships:** Provide forums for and facilitate collaborative discussions between regional bodies, MOH, customs, law-enforcement, Interpol for the purpose of better understanding and preventing illegal cross-border trade. Share lessons learned and best practices from other regions that have been successful in realizing improvements and mitigating risks.
- **Support performance-based supply chain management:** Establish clear performance expectations for health product supply chains that serve as the basis for monitoring and evaluation. Prioritizing funding and resources for capacity building based on target performance outcomes. Where appropriate, collaborating with country institutions to develop private sector capacity.
- **Provide technical expertise on good supply chain practices:** Provide guidance on practices related to chain of custody, inventory management and quantification and distribution planning that should be institutionalized through the development and enforcement of standard operating procedures.
- **Improve partner coordination and collaboration on procurement and quantification:** Harmonize and align procurement requirements across donors. Agree on reporting standards and systems requirements that enable monitoring of the availability of medicines.

Next Steps

The Global Fund leadership called upon meeting participants to commit to leveraging the outcomes of the meeting to inform their work to prevent and combat theft and illegal diversion of medicines, underlying the joint responsibility to take action. The following next steps are proposed:

- Ministries of Health and public health leaders will develop and refine country action plans based on the discussions and incorporating the recommendations from the stakeholders' meeting in Addis Ababa, and will immediately begin implementing mitigation measures that will address underlying causes, risk and enabling factors of theft of medicines.
- The Global Fund will incorporate the risk factors and successful preventive measures identified through the LFA risk assessments, and the recommendations for the prevention of theft and illegal diversion of medicines, into its Operational Risk Management framework to ensure systematic and consistent assessment and management of drug theft risks across the Global Fund portfolio.
- The Global Fund, USAID, technical partners, law enforcement agencies, civil society organizations and the private sector will support countries in this important endeavor, particularly in implementing country action plans and support cross-border and regional cooperation.
- The Global Fund will convene a follow-up meeting to be held alongside the World Health Assembly in Geneva in May 2012 in order to review progress, share ongoing experiences and reinforce engagement to the initiative.

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