

Frequently Asked Questions - Counterfeits

Q: What are counterfeit pharmaceuticals?

A: According to the World Health Organization (WHO), they are medicines that are manufactured below standards of safety, quality and efficacy and are deliberately mislabeled. In most cases, counterfeiting involves replacing active ingredients with the wrong quantity or ingredient, rendering the drugs ineffective at best and potentially life threatening at worst.

Q: How big of a problem is counterfeiting?

A: The scope of the problem is difficult to quantify, but the US Food and Drug Administration and WHO estimate that up to 25 percent of all medicines in the developing world may be counterfeit, which equates to a global market worth in excess of \$35 billion per year and potentially millions of patients at risk of receiving substandard or fake medicines.

Q: Are counterfeit antiretrovirals (ARVs) a problem?

A: The high-cost of ARVs combined with the high demand for these life-saving medicines in the developing world makes them a target for theft and counterfeiting. Generic ARVs, because they generally cost much less than brand-name ARVs, are at less risk of counterfeits.

Q: Where can counterfeiting occur in the supply chain?

A: In a supply chain, there are numerous points where drugs are vulnerable to corruption, from the manufacturing factories to the warehouses or clinics where they are stored. During transport, deliveries are subject to hijacking or theft.

Q: What are some ways to prevent counterfeits?

A: Maintaining a tight chain of custody with control from the manufacturer to the final destination is essential to preventing counterfeit medicines. Short, secure supply chains reduce the potential for diversions and substitutions. SCMS has implemented industry-standard security procedures to ensure the safety of the commodities that we procure for clients. In addition, quality testing and examinations are vital. For the most part, drugs procured by SCMS are picked up directly from the manufacturer and sent to one of four regional distribution centers (RDC) that house shipments for nearby PEPFAR countries. Upon entering the RDC—or after customs when shipments are directly delivered—SCMS conducts selective sampling and physical examination of the drugs. Once in the warehouses, additional security measures include cataloging and stacking as well as segregating staff duties to prevent drugs from being stolen and substituted with counterfeits. During transport, routes and trucking schedules are carefully planned to avoid vulnerabilities. Some drug distributors also utilize serial numbers—from the pallet down to the

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individual packets—for authentic drugs, which are then tracked using methods like Radio Frequency Identification tagging.

Q: What are some improvements you would like to see in supply chain security?

A: Securing the supply chain needs to occur in conjunction with greater attention and efforts by international agencies and governments to combat counterfeit drug trafficking. This is a global problem and requires a global solution with diligent local application. We need to examine techniques which empower health workers and eventually patients to discern authentic from fake or substandard medicines.

Q: What has been SCMS's success rate so far in preventing counterfeits?

A: From October 2006 to February 2007, drug samples were analyzed at the quality testing laboratory at North-West University (an SCMS team member) in South Africa. There were no detections of counterfeit products. To date, SCMS has no reports of lost stock at our RDCs. By ensuring an efficient and secure supply chain to prevent counterfeits, SCMS not only delivers but protects the essential medicines that our clients depend on.

Answers provided by SCMS Freight & Logistics Manager Iain Barton, MD and SCMS Principal Quality Assurance Advisor Tom Layloff, PhD.

For more information: download the Global Health Council's *AIDSLink* by Iain Barton: "Feature: Forging the HIV/AIDS Chain: Securing Safe Passage of Drug Supply in Africa" <http://www.globalhealth.org/publications/article.php?id=1634> or write to SCMSinfo@pfscm.org.