

Quality Assurance

Implementing a system to ensure quality products in the supply chain

A robust quality assurance (QA) system ensures the efficacy and safety of HIV/AIDS medicines and supplies for care and treatment. A functioning QA system also improves supply chain processes and effectiveness. The Supply Chain Management System (SCMS) emphasizes product quality in everything we do, from the commodities we procure to our internal processes and the management systems we use.

The Challenge

The lack of an effective QA system poses numerous concerns for health care providers, including:

- Compromised product quality, from counterfeit or expired products to lack of dosage uniformity and inappropriate labeling and packaging
- Poor warehouse practices that can lead to product waste, damage, expiration, diversion and inability to control inventory
- Differences in climatic conditions in warehouses or during distribution that can cause products to spoil

These challenges can lead to unreliable and unpredictable commodity deliveries to those providing care and treatment to people living with HIV/AIDS. Without a QA system in place, there is no one responsible for monitoring, documenting or reporting on product failure or adverse events. This lack of visibility into the status of products—their storage conditions, expiration dates, quantities on hand and usage rates—contributes to loss of quality control, and can risk the lives of patients who receive inferior quality drugs.

Meeting the Need

SCMS's QA system encompasses everything needed—including the products, the processes and the people—to manage and control all aspects of the supply chain.

A relentless focus on quality ensures that HIV/AIDS programs receive effective medicines, HIV tests, and other commodities for the people they serve.

QA processes for SCMS procurements. SCMS insists on quality products for every client. All products that we procure are obtained from manufacturers whose facilities comply with World Health Organization Good Manufacturing Practice regulations. All antiretrovirals purchased are either approved or tentatively approved by the US Food and Drug Administration (FDA). All medicines for opportunistic infections and sexually transmitted infections are purchased from companies in countries with stringent regulatory authorities or from rigorously controlled wholesalers. Working closely with WHO we strive to improve packaging and labeling guidelines to make them more appropriate for the country context. We also consult with WHO on ways to harmonize products and registration procedures across countries to facilitate product testing

and information sharing.

SCMS uses state-of-the-art QA methods to ensure the quality of all products we deliver to clients. These include:

- Product sampling at any point in the supply chain, including at the manufacturing site, at time of receipt or shipment at the regional distribution centers, at points of delivery and at points of use
- Incident analysis to investigate adverse events when they occur that could impact quality and to implement corrective actions
- Client complaint analysis to investigate and institute corrective actions
- Product quality surveillance to monitor and analyze temperature and humidity at warehouses and during transportation
- Rigid requirements and well-defined processes for recalls, returns and product disposal

Product testing. SCMS team member North-West University provides essential laboratory support. Based in South Africa, North-West is a WHO-qualified laboratory and is certified compliant with International Standard Organization (ISO) 17025. The university offers world-class, risk-based QA analysis, sampling and testing methods to ensure the quality of pharmaceuticals. We also partner with the US Centers for Disease Control and Prevention (CDC) to develop specifications and standards for lab equipment, rapid test kits and reagents.

Security. Products are protected throughout the chain of custody to prevent counterfeiting, theft or product substitution. SCMS regional distribution centers in Ghana, Kenya and South Africa are state-of-the-art, temperature controlled facilities equipped with advanced physical and informational security measures. These include, for example, electronic surveillance, procedures to minimize opportunities for theft and information systems to track inventory.

QA technical assistance. SCMS also bolsters the capacity of host-country governments and organizations to strengthen or establish supply chain systems that ensure quality. We work with local drug regulators to develop standard operating procedures, train staff and register

products in-country. We can provide technical assistance to local quality control laboratories to strengthen the quality assurance of pharmaceuticals used in the country.

Internal SCMS QA processes. Recognizing that our quality system must begin internally, SCMS uses standard operating procedures and work instructions, trains staff to ensure that our processes are reliable, and follows a well-defined document management system with policies and controls. All QA systems we use conform to ISO standards and all procurement systems adhere to US government standards and regulations. Our robust management information system manages the flow of products from manufacturers to recipients.

Sustained Benefits

SCMS consistently offers high-quality products and services, significant product surveillance and transparent information sharing. We proactively partner with vendors to disseminate factual information on product counterfeiting, diversion or substitution. Our relentless focus on quality results in improved product quality, reduced costs and enhanced supply chain efficiencies—ultimately benefiting the people served by HIV/AIDS prevention, care and treatment programs.

ABOUT SCMS

The Supply Chain Management System (SCMS) was established to collaborate with in-country and global partners to ensure a reliable, cost-effective and secure supply of high-quality medicines and health products for HIV/AIDS prevention, care and treatment. SCMS is funded as part of the US President's Emergency Plan for AIDS Relief through the US Agency for International Development. Visit www.scms.pfscm.org or write to scmsinfo@pfscm.org for more information.

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