



**USAID** | **KENYA PHARMA**  
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# KENYA PHARMA PROJECT

## YEAR I ANNUAL REPORT

**JULY 2010**

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# KENYA PHARMA PROJECT

**YEAR 1 ANNUAL REPORT**

**Contract No.623-C-00-09-00014-00**

**[www.kenyapharma.org](http://www.kenyapharma.org)**

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## ACRONYMS

API	active pharmaceutical ingredient
ART	antiretroviral therapy
ARV	antiretroviral drug
AZT	azidothymidine or zidovudine
e-SCM	electronic supply chain management
KEMSA	Kenya Medical Supplies Agency
MEDS	Mission for Essential Drugs and Supplies
NASCOP	National AIDS and Sexually Transmitted Diseases Control Program
NQCL	National Quality Control Laboratory
OI	opportunistic infection
PEPFAR	the President's Emergency Plan for AIDS Relief
QA	quality assurance
SDP	service delivery point
USFDA	U.S. Food and Drug Administration
WHO	World Health Organization

## EXECUTIVE SUMMARY

In its first year of operation, USAID's Kenya Pharma Project has created an effective distribution channel in the country for HIV/AIDS commodities. The project has developed a sustainable supply chain management system to support the Kenyan government's current ability to respond to the country's health needs. The system is capable of accommodating a wide range of commodities and of being transferred to the government when the project ends. Thus, the project worked on two levels: fulfilling immediate needs, while building a permanent foundation for the future.

The project has delivered critical high-quality first-line antiretroviral (ARV) drugs for the care and treatment of more than 180,000 adult HIV/AIDS patients supported on first-line ARVs by the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), exceeding the original target ceiling for the three-year base contract. This excludes indirect support to supply chains that provide second-line and pediatric commodities.

### Key Accomplishments in Year 1

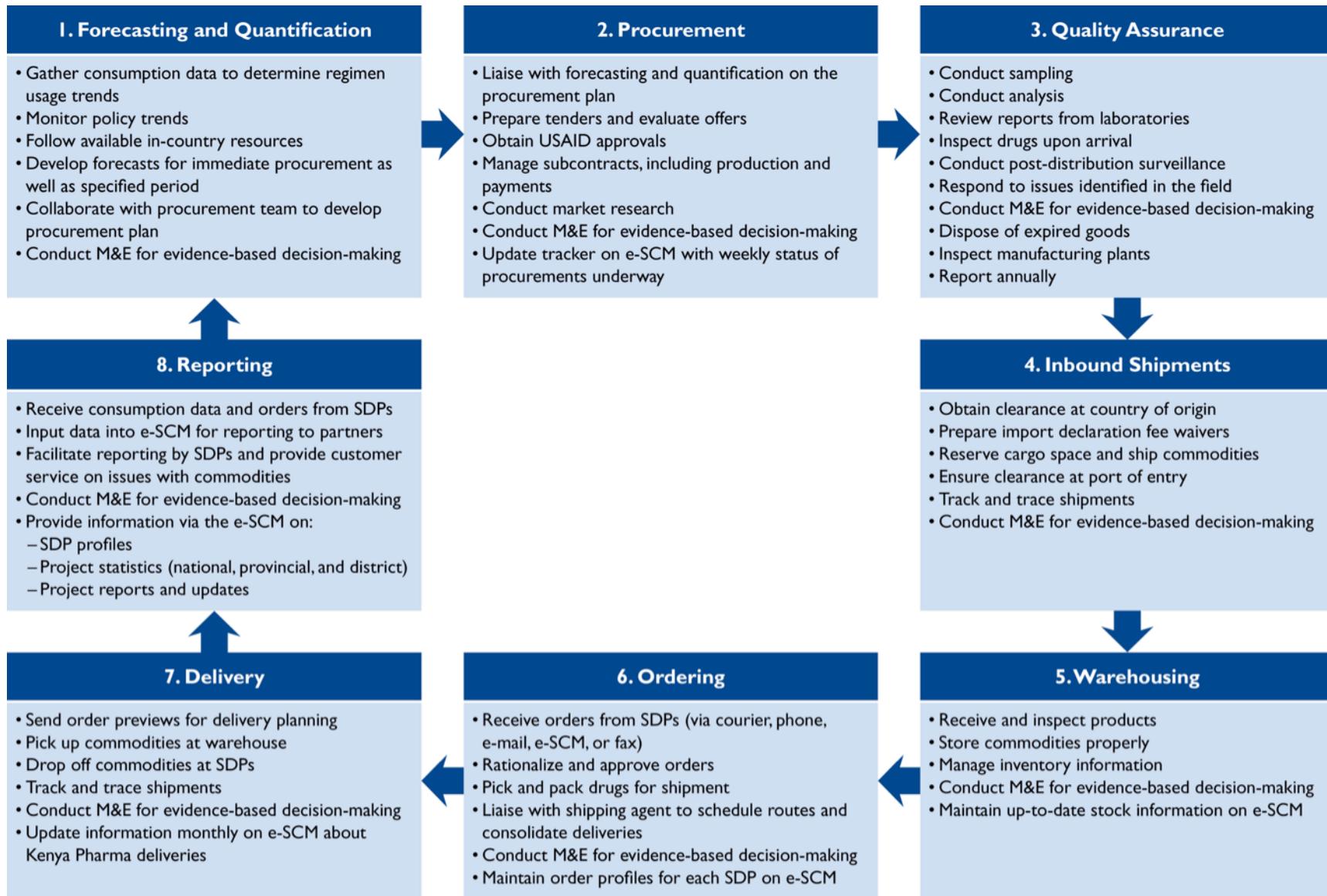
- Rapidly launched responsive, proactive processes
- Brought innovation in real-time data-sharing through creation of a field agent network and Web-based management information system
- Supported the Kenyan government to fill gaps in supply of ARVs and opportunistic infection (OI) drugs

During the year, the project developed flexible and responsive systems to establish and ensure a sustainable supply chain with accurate forecasting; a competitive, transparent procurement process; reliable, high-quality commodities; precise order management and warehousing; and efficient shipping and delivery. (Please see the project's process map in Exhibit 1 on the next page.) Two innovations are key to its success.

*Field agents.* To facilitate communication with service delivery points (SDPs) and provide personalized customer service, the project hired a team of field agents. Their role is to ensure reliable supplies are delivered to SDPs and that critical data are collected to help with forecasting for procurement and order fulfillment. Each field agent has been assigned to specific facilities and is supervised by a regional manager. The field agents give medical staff and SDP managers someone to talk to about issues related to the drugs Kenya Pharma supplies. Through monthly visits and frequent phone calls and text messages, they facilitate timely collection of qualitative and quantitative information that the project shares with stakeholders. Their service ethic means most orders are delivered within 24 hours of being packed and data are reported for quantification and forecasting.

*Electronic supply chain management system (e-SCM).* To improve the efficiency of all processes and link them, Kenya Pharma created a real-time Internet-based supply chain management system, accessed at [www.kenyapharma.org](http://www.kenyapharma.org). The system facilitates transparent, accessible external information-sharing and essential internal operational management and control. The e-SCM draws information from all partners, beginning with SDP order placement and consumption data input and ending with SDP receipt of

**Exhibit 1. Kenya Pharma Process Map**



stocks. The initial phase focused on meeting the needs of clients so they can access their stock and order information and submit orders online. The project completed a draft layout in January, and the system was fleshed out and populated with data in subsequent months. The current phase of e-SCM development is focusing on developing the procurement, forecasting and quantification, and quality assurance (QA) elements of the system, which are used internally for supply chain management.

Immediately upon award, the project leased a central warehouse, obtained Ministry of Health approval for it, and hired and trained warehouse staff. Project staff worked quickly. At the end of Month 1, more than \$11 million in commodities from Mission for Essential Drugs and Supplies (MEDS) had been transferred to the warehouse, and an inventory of the supplies had been taken. Incoming MEDS orders still arriving from suppliers were also re-directed to Kenya Pharma.

A strong order management team at the warehouse and the project logistic team's ability to respond immediately made it possible for the first truckloads to SDPs to leave on August 18 — just a few days into Month 2. The first order was received within one day, setting a standard for the rest of the year.

By December, the project had compiled a database from SDPs, including inventory and the number of patients at each clinic, to serve as the basis for initial forecasting. Staff then developed forecasting and procurement processes to respond quickly to changing priorities and evolving stakeholder and beneficiary needs. When the project began to respond to short- and long-term requests from the Kenyan government, staff used fast-track ordering and, in some cases, rationing, to ensure that no PEPFAR sites or PEPFAR patients at dual PEPFAR-Kenya Medical Supplies Agency (KEMSA) facilities were without the required ARV drugs throughout the year.

In September, Pharma began writing standard operating procedures for the entire procurement, delivery, and QA process. The procedures ensure procurement of the safest medicines and that storage and handling processes follow international quality standards, providing inbound and outbound QA from procurement to end-user. Vital for guaranteeing consistent actions, the procedures were adapted during the year to serve the needs of the supply chain.

**Standard Operating Procedures**

- Forecasting and quantification
- Procurement
- Order management
- Client services
- Storage and inventory
- Quality assurance

The project purchases drugs on a best-value basis. Staff regularly compare prices with those reported internationally by the Clinton Foundation or the World Health Organization (WHO) Global Price Reporting Mechanism, with the aim of keeping prices within an average of 10 percent of indicator prices for similar products procured under similar terms. At times, the project does not take the lowest offer, to ensure that deliveries will be on time and quality will remain high.

Kenya Pharma has also emphasized supply chain efficiencies, introducing consolidation of delivery loads in March. Load consolidation was possible only after in-depth research on the exact locations of the SDPs, designation of clusters of facilities, and design of logical delivery routes.

Staff quickly established relationships with key ministries, and a project stakeholder workshop in August gave participants a chance to discuss expectations and collaboration. Kenya Pharma works in partnership with the public sector and is a key player in a monthly meeting hosted by the National AIDS and Sexually Transmitted Diseases Control Program (NASCO), providing commodity supply and patient information to government partners. Staff also support other HIV/AIDS supply chains to serve as many patients as possible and ensure continuity of care in case PEPFAR-supported patients require second-line regimens. For example, the project directly supports the Kenya Medical Supplies Agency (KEMSA) via supplies and indirectly supports the Clinton Foundation through information transmission.

A challenge during the year was WHO’s recommendations for a change in antiretroviral therapy (ART) guidelines. The WHO decision was made public in December, and some patients refused the old regimen the next day. The project, however, was committed to following Kenyan government guidelines, which remained the same. Manufacturers were also not prepared to meet the massive global increase in demand for the alternate regimens. Now, through the recent National Forecasting and Quantification Exercise, stakeholders are quantifying at the national level how to respond to the new guidelines during a transition period. In mid-July, a circular endorsing the revised ART guidelines was released. The guidelines were expected to be finalized soon and disseminated to all stakeholders.

The challenging year has provided Kenya Pharma with opportunities to fine-tune its processes and augment its knowledge of supply needs. Each day brings new insights into the complexities of the environment in which the project works. With its strong, flexible framework, the project welcomes those opportunities. Kenya Pharma has a solid relationship with its partners, all parties understand their roles, and staff are ready to meet new challenges in Year 2.

<b>Kenya Pharma Partners</b>
Chemonics International Inc. <ul style="list-style-type: none"><li>• Overall project management and oversight</li><li>• Relationships with USAID, Kenyan government, other donors</li><li>• Monitoring and evaluation, project communications, reporting</li></ul>
DHL Supply Chain Ltd. <ul style="list-style-type: none"><li>• <i>Inbound</i> Shipping, clearing, forwarding, tracing, and tracking</li><li>• <i>Outbound</i> Delivery, tracking, documentation, reporting</li></ul>
Phillips Healthcare Services Ltd. <ul style="list-style-type: none"><li>• Forecasting and quantification</li><li>• Procurement</li><li>• Warehousing, order management</li></ul>
Vimta Labs Ltd. <ul style="list-style-type: none"><li>• Drug analysis for quality assurance</li></ul>

## SECTION I. PHARMACEUTICAL PROCUREMENT PLANNING

A team of recognized experts in their fields, combined with comprehensive, integrated, systematic processes, give Kenya Pharma the ability to accurately quantify and forecast needs, procure commodities transparently and cost-effectively, ensure meticulous quality analysis, track inventory precisely, and respond immediately to orders from SDPs. The team's experience with USAID, NASCOP, and HIV/AIDS nongovernmental organizations in Kenya means they are aware of and work within the realities of the country.

From order placement through delivery, the project's two local partners, DHL and Phillips, work together to ensure a smooth process and the ability to deliver commodities in one day. During the year ended in July, Kenya Pharma delivered 360,000 kg of commodities to 190 central facilities, which redistributed supplies to 160 satellite sites, for a total of 350 sites served. Included in that total are 102 dual sites that receive both Kenyan government and PEPFAR supplies. Supporting KEMSA sites was not part of the original plan, but the project was able to procure for KEMSA for three months, with ad hoc, daily deliveries.

The e-SCM will enhance the entire process, providing a tool to manage procurement and order management, and improving access to warehouse inventory data and SDP stock information. It also will give SDPs the ability to report, order, and see what they have received and consumed.

The project's staff and infrastructure make it possible to prepare for and adjust quickly to changing circumstances and to external developments. Each step in the process is continually refined as the environment evolves.

### Forecasting and Quantification

The experienced forecasting and quantification staff work with stakeholders and partners to ensure that project orders mesh with and support its own patients, other portions of the sector, and changes due to shifts in treatment recommendations, continuing growth in the patient population, and conditions in the international marketplace.

The staff make informed projections of needs, based on consumption patterns, data on warehouse inventory, average lead times for ordering commodities, existing stocks at SDPs, and their knowledge of the wider commodity environment. They review warehouse inventory levels daily and more thoroughly after each monthly distribution cycle. This assists with subsequent order management and distribution.

At the project's inception, staff determined which facilities were PEPFAR-supported, which were KEMSA, and which were supported by both supply chains. They also compiled a database of existing stocks and the number of patients at each facility. These steps were necessary to begin accurately forecasting needs.

Now, each month, each SDP reports on its stock levels and places its order. If the forecasting and quantification staff see that an SDP has not ordered or has low stocks, they will check with the facility. Staff then capture and analyze data from the order forms — what has been consumed, what has expired, the level of stocks, the level of previous consumption, and the number of patients. These data assist in forecasting the SDPs' future needs, including adequate buffer stocks. Ideally, SDPs hold a three months' supply at any time: two months of buffer stocks and one month of dispensing stocks.

In addition to daily inventory control checks at the warehouse, technical staff conduct stocktaking quarterly, comparing book records with a physical count and deliveries. Staff also check shipments as they arrive at the warehouse, make notes on any damage or shortages, and take action with the responsible parties to reduce losses.

Health professionals knew the WHO might change its guidelines and recommend a phase-out of stavudine-based regimens, but premature media coverage of the change on World AIDS Day (December 1, 2009) confused patients and health care personnel alike. After that date, few new patients were started on stavudine, and a majority were started on a zidovudine (AZT)-based regimen. This was a major departure from trends that had informed previous forecasts.

Following the shift in regimen usage, Kenya Pharma began emergency quantification in line with guidelines decided at a meeting hosted by NASCOP in January. Because the government's intentions were not disseminated to the field, trends on the ground were shifting in a different direction, in favor of AZT-based regimens. This was one reason that it was difficult for Kenya Pharma to obtain AZT-based drugs to meet the demand, as these trends had not been anticipated. When the trend was identified, the project had to adhere to its procurement procedures, and manufacturers lacked the capacity and sufficient active pharmaceutical ingredients (APIs) due to the global shift. To continue to meet needs, Kenya Pharma had to stretch available commodities to cover as many patients as possible and avoid treatment interruptions as staff initiated fast-track procurements. One step taken was to reduce buffer stocks, so that instead of some SDPs holding three months of stock while others had none, Pharma ensured each facility was covered. To enable emergency deliveries, backorders were processed and delivered as soon as the warehouse received AZT-based commodities, ensuring continuity of care.

Pharma is prepared to shift its orders to comply with the expected new Kenyan government guidelines, which would phase out stavudine-based regimens during the next three years. The project has planned procurements accordingly, initiating early procurement for the phase-in of recommended tenofovir (TDF)-based regimens and sufficient AZT-based regimens to respond to trends.

When the project's mandate was expanded to include OI drugs, staff immediately began compiling historical usage data on which to base forecasting. There was no finalized list of recommended OI drugs, so USAID rationalized the list. NASCOP has since proposed about 20 OI commodities, which PEPFAR was expected to reduce soon to cover five key OI conditions.

## Procurement

The project's procurement processes are transparent, allow broad participation from eligible suppliers, and result in best value to the government. Kenya Pharma conducts an extensive review of each tender leading to a best-value award. The project advertises for bids with an e-mail to qualified suppliers and via newspaper ads. Upon award, each bidder is informed of the name of the winner and the price accepted. The project released its first request for proposals on August 19, 2009, to fill a gap in existing MEDS stock, and issued 10 procurements during its first year.

It takes an average of six months from issuance of the request for proposals until the commodities are received at the warehouse. There was a four- to six-week lead time at manufacturers, but now that is more than 18 weeks, so Pharma is splitting its orders between suppliers to ensure availability. Sometimes there are only one or two U.S. Food and Drug Administration (USFDA)-approved suppliers for a specific drug.

The project buys ARVs from USFDA-approved suppliers in India, many of which visit Kenya Pharma in Nairobi every few months. The team is in constant contact with the manufacturers about mutual challenges and the supply and demand situation, so the suppliers are more aware of trends, new product requirements, and the level of demand. To maximize project savings due to constant price reductions, procurement has been on an as-needed basis, and the manufacturers have been responsive.

Pharma issued its first OI request for proposals in November. It was open to local manufacturers to provide potential local capacity development and promote long-term sustainability and cost-efficiency. However, the project conducted 100 percent batch testing, because the suppliers were not USFDA-approved. The small batches, limited production capacity, and 100 percent batch testing requirement meant that QA procedures took a long time. As a result, procurements from the local manufacturers were not timely. The project moved to USAID pre-approved international suppliers Mission Pharma and International Dispensary Association, but found both were using the same manufacturer, creating a three-month lead time. The project would like to work with the local suppliers to help them be better able to help meet the demand for OI drugs, which will result in better local supplies.

Pharma staff continually monitor Web sites for USFDA approvals of new manufacturers and follow the PEPFAR expedited review process. Manufacturers also update Pharma on the approval status of their products and local registration. Pharma maintains a database of new registrations by the Pharmacy and Poisons Board and of USFDA approvals.

In the transition to the new ARV regimen, stakeholders will share what stock is left instead of buying more old stock. When the project started, 70 percent of Kenyan patients were on stavudine-based regimens, which now will be phased-out; 25 to 30 percent were on AZT; and TDF was a second-line treatment. Now, TDF is moving to a first-line drug and may be on an equal footing with AZT. Pharma has made provisional projections for needs, but is waiting for the official guidelines, expected in the next few weeks, before placing orders.

## Inbound Shipments

Pharma is one of the many projects and organizations that buy drugs from India. Shipments come from Bangalore, Bombay, Hyderabad, and Pune, but there is limited cargo space, because Emirates Sky Cargo is the only airline with capacity. Because there are no direct flights from India to Nairobi, if cargo is booked one day, it arrives two days later, after a stop in Dubai.

The Kenyan government has not given a blanket duty-free tax waiver, so one must be obtained for each consignment. This takes about two weeks. To speed up the process, the project conducts QA testing and applies for the tax waiver while the products are still at the manufacturers. The project books cargo space after it receives the waiver. Shipping, customs clearance, and receipt of drugs at the Nairobi warehouse take five days, sometimes less if clearance is quicker.

As orders arrive at the warehouse, project staff conduct 100 percent verification of incoming shipments to ensure manufacturers adhered to contract requirements and there was no damage during shipment. Chemical analysis is done while cargo is being booked and shipped, so by the time the product arrives, the analysis is complete or close to complete.

One challenge is the time it takes for analysis of products. This has been an issue for Vimta, but the project helped the company establish a more efficient QA system to diminish delays. From March to May, Vimta analysis was delayed because it was undergoing an USFDA audit. Since the audit has been completed, analysis is occurring more rapidly.

## Outbound Deliveries

Kenya Pharma received MEDS stocks at the central warehouse on August 3 and made its first deliveries on August 18, ensuring patients were able to obtain the drugs they needed during the changeover from the previous supply chain.

When an order is received, warehouse staff acknowledge it. Before an order is dispatched, staff at the warehouse rationalize it, asking whether the SDP is requesting the correct amount based on its consumption pattern and projected needs, as well as whether the number of patients reported is correct. Sites with both PEPFAR and KEMSA patients sometimes submit the same numbers twice, so that has to be checked to avoid double



Each order undergoes four strict checks at the Kenya Pharma central warehouse before it is dispatched to the SDP. Efficient processes mean this is usually completed within 24 hours of receipt.

deliveries. If an order is changed, Pharma staff clarify exactly what drugs will be delivered and specify when they will arrive, allowing the SDPs to plan for their patients. “With Kenya Pharma, I am organized. I know what I will get,” said Serah Gathu, ART pharmacist at Mbagathi Hospital.

Kenyan government guidelines stipulate that SDPs should submit their orders by the 5th of the month. Warehouse staff track orders; on the 5th and the 10th of each month, they compile a report listing the sites that have not sent orders on time. Field agents then contact delinquent facilities to remind them to submit their orders and to offer assistance in preparing them. Only 27 percent of SDPs ordered during the first week of March, when field agents were just beginning their work, compared with 69 percent in the first week of July. Compliance with the reporting deadline helps with delivery planning, load consolidation, and maximum use of truck capacity, cutting delivery costs and times. Once orders are verified, “picking and packing” the commodities takes two days. Warehouse staff make certain that packing lists and delivery notes are correct. This is a critical step, because many deliveries go to remote areas. The delivery notes contain details of each commodity, with the amount, value, and expiration date.

During Pharma’s initial months, many deliveries were by courier — single and ad hoc — with orders processed as they came in, to begin to stabilize supplies. At the same time, field agents mapped the 350 PEPFAR SDPs served by the project, recording global positioning system data. The project also mapped additional field sites near those to be served, in anticipation of an expansion in Year 2. Mapping and map production started in November and was completed in April.

Once the maps were complete, the project designed 16 primary delivery routes incorporating the SDP clusters, for efficient delivery, larger loads, and lower costs. From March to May, a pilot load consolidation exercise showed immediate positive results. Before load consolidation, half of all delivery trips were on an ad hoc basis. Since load consolidation began, nearly 75 percent of deliveries have been consolidated loads.

Pharma’s target is to send two to three dispatches a month — one every five days after load consolidation. An average of 149 orders is filled each month. If orders are submitted on time, there is a better opportunity to consolidate loads, but there are sometimes ad hoc urgent requirements.

Exhibit 2 on the following page presents the project’s record on delivery times, showing performance at consistently high levels.

## **Stocks**

Kenya Pharma overcame numerous external challenges in keeping adequate stock and buffer stock levels in its first year. They included the WHO guidelines revision, manufacturing slowdowns in India due to political unrest, insufficient air cargo space, delays in shipments caused by ash from the Eyjafjallajokull volcano in Iceland, and manufacturers’ lack of capacity and APIs. These could affect supplies for two or three months, and Pharma took the necessary steps to mitigate any adverse effects.

## Exhibit 2. Delivery Statistics

Month	Number of Orders Processed	Orders Delivered Within 24 hours of Loading	Orders Delivered Within Five Days of Loading	Average Number of Days from Warehouse to SDP
August	97	86%	99%	1.34
September	103	100%	100%	0.89
October	156	100%	100%	1.00
November	131	99%	100%	1.04
December	147	97%	100%	1.07
January	137	96%	99%	1.23
February	129	99%	100%	1.35
March	123	99%	100%	1.07
April	132	98%	100%	1.10
May	180	96%	99%	1.19
June	271	98%	100%	1.09
July	187	100%	100%	1.00
<b>Total</b>	<b>1,793</b>	<b>97%</b>	<b>100%</b>	<b>1.10</b>

Rationing of supplies was one such step. By focusing on critical ARVs and by limiting some patients to a week's, rather than a month's supply, at a time, the project ensured drugs were available when patients arrived at facilities. Some SDPs also borrowed from each other when needed to ensure availability.

The project adjusted its payment policy to speed up some deliveries. Previously, payment was made when the drugs were delivered to the warehouse, but to ensure that payment arrived at the manufacturers as soon as they completed their duties, Pharma started authorizing invoicing upon receipt of QA. In addition, the project began to allow delivery of the commodities before receipt of QA if manufacturers agreed to present a letter of undertaking stating that if the drugs were sub-standard, the manufacturer would bear any related costs. The manufacturers are USFDA-approved, so there is little likelihood of non-compliance. Pharma began modifying contracts in May to incorporate this change. This cuts two weeks from the process.

**More Stable Supplies**

“The patients, they don't go from here without drugs, and we don't have to borrow from other facilities, since Kenya Pharma started.”

— *Fredrick Ochenge,*  
*pharmacist,*  
*Tabitha Health Centre, Kibera, Nairobi*

Current stock levels have not been fully restored to desired levels because of the phase-over to the new regimen. Facilities have not had their normal two-month buffer stocks of AZT/3TC and nevirapine for the last two months. However, shipments were scheduled to arrive in July, with the level stabilizing in August.

KEMSA was also forced to ration earlier this year. However, when KEMSA cannot meet its needs, it orders through USAID, which instructs Kenya Pharma to provide the commodities, sometimes sending out an extra load.

SDPs report that before Kenya Pharma, the shelf life problem was critical, and they had to share commodities with other facilities to use them before they expired. Kenya Pharma commodities have 70 percent of their shelf life remaining.

The e-SCM offers a way for stakeholders to better manage their stocks, consolidating real-time data that begins with the input of each SDP's procurement, storage, and delivery information. At the SDP level, each facility can see the status of its own order and the amount of Pharma stocks for each drug at the warehouse. At the district level, pharmacists and district medical officers can see their consumption of ARVs and OIs by region, as well as each SDP's stock levels, so the district can transfer stocks within itself and see soon-to-expire stocks. At the national level, the government and other stakeholders can see constantly updated stock levels to help with planning and policy decisions.

#### **Dual Sites Benefit from Pharma**

"If we don't get enough from KEMSA, I call Kenya Pharma. I spoke to (the project's central warehouse) on Thursday, and on Friday, I had the drugs."

— *Serah Gathu,*  
*ART pharmacist,*  
*Mbagathi Hospital, Nairobi*

## SECTION II. PHARMACEUTICAL QUALITY ASSURANCE

Project staff with long-term experience in Kenya, including with KEMSA, established a stringent QA process to oversee the procurement, manufacture, shipment, storage, and delivery of consistently high-quality commodities, including handling and storage at the SDPs. There have been minimal quality issues, none toxic, and all were caught and dealt with immediately by the QA team. The team's expertise and the project's meticulous recordkeeping made this possible.

For the first few months, Pharma followed existing practices and ensured the shipping and QA process was as smooth as possible. All products procured by Kenya Pharma are released for distribution only after satisfactory laboratory analysis.

Testing of the commodities comprises three steps:

- Sampling a certain percentage of batches, as per ISO 2859 – 1:1999 standards
- Analyzing the samples to ensure they meet official standards
- Inspecting commodities on arrival at the warehouse

Test parameters are product-specific and follow official monographs, such as the United States Pharmacopeia and British Pharmacopeia. Biological, physical, and chemical tests are conducted.

The field agents play an important role in guaranteeing quality. They forward concerns from SDPs about products Pharma delivers to the QA manager and relay issues the project discovers to the SDPs. The QA manager and the supply chain specialist developed a tool to assess handling and storage at SDPs so that quality is maintained even after the drugs leave the central warehouse.

Early in the year, partner Vimta Labs conducted 100 percent batch sampling, inspection, and analysis of all commodities manufactured in India before they were shipped to Kenya. The percentage of sampling was reduced as the project acquired knowledge about the manufacturers, which are all USFDA-approved. As of the end of June, the project was conducting 5 percent batch testing of drugs manufactured by USFDA-certified suppliers. Reducing the number of batches to be tested will greatly improve the turnaround time for the results. Vimta has agreed to a seven-day turnaround time. For several months, Kenya Pharma sent samples to Vimta and the National Quality Control Laboratory (NQCL) while it identified bottlenecks in the Vimta analysis process



PHOTO: KENYA PHARMA

A pharmacist at Mbagathi District Hospital prepares to distribute Kenya Pharma drugs. The project has supplied consistently high-quality commodities.

and delays in clearing samples that were sent to India. The biggest QA issue was with Vimta undergoing a 45-day USFDA audit, which involved time to prepare for the audit and take corrective action afterwards. This caused analysis delays from March through May. Vimta was back on track in early June, at which time the project resumed sending samples to Vimta. However, if Vimta's laboratory reaches capacity again, Pharma will use NQCL or MEDS, although MEDS can analyze only tablets, not syrups or suspensions.

For OIs, the team assesses the local suppliers, manufacturing sites, and products. This QA oversight is helping manufacturers increase the quality and consistency of their products, processes, and packaging, which will benefit the health of the country's population in the long term. The project QA manager has conducted 100 percent batch sampling and inspection for locally manufactured drugs, plus random on-site sampling of the two local suppliers' manufacturing processes and quality control procedures. However, the project is working toward reducing this percentage.

The products received from MEDS were sampled randomly and taken to NQCL for laboratory analysis. Out of the eight batches NQCL analyzed, one batch of fluconazole tablets failed to comply with the dissolution parameter. The results were released by the lab in March 2010 (a sample was taken for analysis in September 2009), and by then the product had been distributed and consumed by the facilities.

Pharma has recalled one drug: three batches of locally manufactured ciprofloxacin 500 mg tablets. This OI drug had been certified by the manufacturer and by Vimta was released for distribution; a month later, NQCL said the drug did not comply. Pharma immediately put a hold on warehouse stocks of the drug and told SDPs not to issue any more. The manufacturer, Universal Corporation Ltd., and Vimta then re-analyzed and also found non-compliance. The drug's coating had hardened during the month, preventing dissolution of the medicine. It did not, however, produce any toxic effects to the patient. Kenya Pharma notified SDPs within three days not to distribute the drug, and picked up remaining supplies during the next delivery cycle. The manufacturer has issued a comprehensive investigation report explaining the reasons for the non-compliance and is scheduling the replacement, which is expected to be completed by the end of August.

The remaining 34 products analyzed (with 100 percent batch testing for every product) complied with the full monograph of test parameters.

SDPs reported nine QA concerns during the year. Similarity in the packaging of different drugs was the main concern raised about Pharma drugs. These concerns were addressed by giving the facilities a comprehensive explanation of the project's procurement regulations, which result in such similarities, and offering advice on how dispensers could help patients differentiate drugs. There have been no actual quality problems with commodities procured by Pharma.

Three of the QA concerns raised by SDPS concerned products procured and distributed by MEDS. These were forwarded to MEDS for further action.

From the onset of the project, all consignments received in quarantine into the Pharma warehouse were randomly inspected for proper labeling, packaging, shelf life, and dosage form discrepancies. In addition, the project compares certificates of analysis from the manufacturer and the independent laboratory. In the fourth quarter, one product failed to comply with packaging requirements as stipulated in the contract, but because the need for the product was great, and the packaging did not compromise its use, it was released for distribution.

## SECTION III. PHARMACEUTICAL PRICE AND OTHER EFFICIENCIES

Kenya Pharma’s procurement procedures ensure competitive pricing, which is verified through several internationally available price databases. Its warehouse inventory control measures and load consolidation process also contribute to efficient procurement and delivery of commodities to the SDPs.

The project compares offered prices at each tender with three to four price indices and generally pays less than the average international market price. In the last tender, the project saved 32 percent on ARV drugs and 19 percent on OIs, when compared with prices shown in the International Drug Price Indicator Guide.

However, procurement staff are careful to balance prices with proposed delivery schedules and the reliability of the manufacturer to ensure best-value purchases for the government. The project selects suppliers according to USAID procedures, plus:

- Product certifications by USFDA
- Product registrations by the Kenya Pharmacy and Poisons Board
- Proposed delivery schedule
- Past performance
- Product cost

Logistics staff saw an opportunity for further cost and time efficiencies. In March, they began a pilot exercise in consolidation of loads delivered to the clinics and hospitals. This was made possible after the project defined four regions and delivery routes along clusters of clinics and hospitals. In addition, it was necessary for SDPs to report consistently early in the month, so deliveries could be scheduled along the routes. That number has increased substantially. (See Exhibit 3 on the next page.)

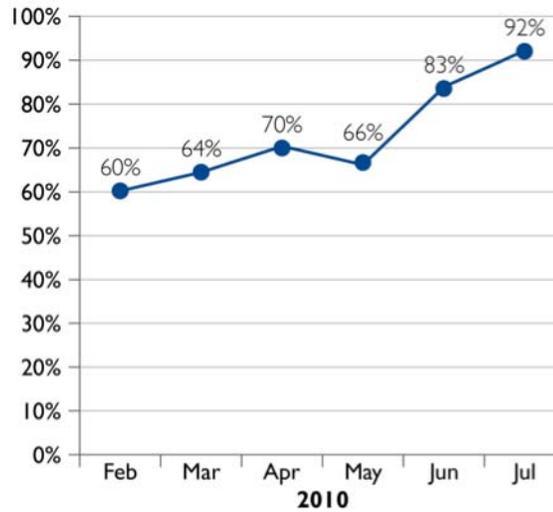
### Load Consolidation

Since Kenya Pharma began consolidating loads for delivery to SDPs in March, the project has experienced:

- Lower distribution costs
- More efficient vehicle usage
- More effective delivery planning
- Enhanced tracking of deliveries

Previously, to meet the 24-hour delivery requirement, a truck left the warehouse each day. From August through February, couriers were used half of the time, as it was uneconomical for DHL to use its own trucks for small loads. Since the load consolidation exercise began in March, that level has dropped to 26 percent. Also since March, the average vehicle load rose to 1,219 kg from 700 kg, a 66-percent increase. A total of 1,800 kg per truck is the most cost-effective weight for pharmaceuticals.

**Exhibit 3. Percentage of SDPs Sending Monthly Consumption Reports**



Strategic partners Phillips and DHL now sit together at the Pharma warehouse and make joint decisions on consolidation; deliveries are normally made two to three times a month. This gives the team time to report and follow up on delivery issues. These structured deliveries also give the facilities enough time to collate the data and report in time for the following month's delivery.

## SECTION IV. COLLABORATION

The project works with all active partners in HIV/AIDS supply chain management in Kenya toward one goal: ensuring the safe, consistent, reliable supply of commodities for patients in need. The project principally works with NASCOP, with whom it shares information and supplies and coordinates on strategic planning. It also supports supply chain partners the Clinton Foundation and KEMSA. In doing so, Pharma has become integrated within the wider AIDS community's decision-making and planning processes.

Project staff are active participants in a monthly commodity security meeting chaired by NASCOP, where procurement stakeholders review stock levels. In those meetings, the Clinton Foundation, KEMSA, *Médecins Sans Frontières*, and Partnership for Supply Chain Management System examine commodities in all pipelines. Kenya Pharma provides much of the information in two-page summaries of the meetings. Patrick M. Wambua, coordinator,

NASCOP HIV/AIDS commodity security, says Kenya Pharma is an important member of the committee, ensuring that the two supply chains are working together as a team.

### Teamwork with NASCOP

"I would rate Kenya Pharma very good. When we have issues with supply, they work very fast. They are part and parcel of us."

— Ibrahim M. Mohammed,  
head, NASCOP,  
Ministry of Medical Services

At NASCOP's invitation, the project participated in a weeklong National Forecasting and Quantification Exercise in June to identify needs for HIV commodities, including drugs, condoms, and laboratory supplies, and to find gaps in supplies so the government can seek funding. Participants examined needs and funds for the next four to five years, to ensure there is a continuous supply of drugs available to patients.

During the year, project technical staff contributed to numerous meetings organized by or alongside:

- the Centers for Disease Control and Prevention
- The Walter Reed Project
- Academic Model Providing Access to Healthcare
- provincial and district pharmacists
- district AIDS and sexually transmitted infection coordinating officers
- provincial AIDS and sexually transmitted infection coordinating officers

Kenya Pharma also supplies commodities to SDPs funded by, among others:

- USAID's AIDS, Population, and Health Integrated Assistance II project
- Columbia University's International Center for AIDS Care and Treatment Program
- Liverpool VCT
- AIDS Relief
- the Centers for Disease Control and Prevention
- Family AIDS Care and Education Services
- Carolina for Kibera

Pharma also works with NASCOP to fast-track registration of new suppliers for particular drugs when the supply is limited or to get a waiver. The project also provides information on Pharmacy and Poisons Board registration requirements and responds to new suppliers' inquiries about the local pharmaceutical industry environment and the status of their applications.

## SECTION V. REPORTING (PROGRAMMATIC/FINANCIAL)

Kenya Pharma's network of field agents and its e-SCM are structural aspects that facilitate reporting and sharing of accurate, timely data and requests with all stakeholders. The field agents excel at customer service, giving constant feedback to the facilities and project staff, and ensuring that orders are fulfilled and data are collected, transmitted, and available for forecasting and procurement. The e-SCM makes their job easier by consolidating the information on a real-time basis.

The field agents were recruited and trained in early October to give SDPs someone local to help with issues related to Pharma's work. Most SDP medical staff did not have someone from the ARV supplier with whom to discuss concerns about their commodity supply, ordering or reporting challenges, or emergency drug needs. Field agents fulfill this role, meeting face-to-face with SDP medical staff.

Efficient procurement requires that orders are submitted on time and that data are accurate; 17 field agents assigned to four regions work to ensure that this happens. The regions are Nairobi/Central, with a regional manager in Nairobi and field agents in Nairobi, Thika, and Nyeri; Nyanza/Western, with a regional manager in Kisumu; Coast/Eastern/Northeastern, with a regional manager in Mombasa; and Rift Valley, with a regional manager in Eldoret. Each region has four field agents, except for Nyanza/Western, which has five. Four regional managers, all with pharmaceutical backgrounds, supervise the field agents.

Each field agent is responsible for 15 to 25 central and satellite sites. The central sites order drugs from Pharma and supply the satellite sites. Kenya Pharma conducted initial data-collection training for the field agents, and holds follow-up quarterly capacity-building to improve data and enhance relationships with SDP partners.

Field agents make at least one visit per month to main sites; they visit more often if they have few total assigned sites. They spend an average of two to three hours at each site, although it can be as little as 30 minutes if there are no issues. Issues are usually addressed immediately, often while the field agent is still at the site. If that is not possible, the agent reports the issue to the logistics team before he or she leaves the SDP.

The field agents facilitate collection of monthly consumption data from central sites, which in turn have gathered and consolidated data from satellite sites. They also conduct storage assessments for both types of sites, looking at such issues as how the drugs are

### The Face of Kenya Pharma

Field agents provide personalized support to SDPs through frequent visits and phone calls. Their three primary roles are to:

**Collect** information on ART patients per regimen and report data on stock quality and levels, treatment targets, and future drug requirements

**Monitor** storage capacity and conditions of assigned SDPs

**Submit** a monthly operations report to the regional manager, highlighting key issues requiring immediate follow-up and feedback from SDPs to improve service delivery

stored, the condition of the building, moisture conditions, or anything that would affect the quality of the drugs. They inquire about reports, orders, and deliveries; facilitate stock rotation to avoid expiries; and ask if there are any issues. They note any drug quality problems or discrepancies in the amount delivered, or other issues, and refer them to Pharma's technical staff in Nairobi. The field agents visit satellite sites strategically when there is an issue to discuss. Because satellite sites sometimes miss their reporting deadlines, the field agents explain the importance of reporting on time.

SDP operators know the field agents personally. Therefore, if they have a question, they are calling someone they know, not an institution. Clinic and hospital staff say they get an immediate reply when they text, call, or e-mail their field agent with an issue. All emergency orders have been responded to within one business day; some have received a response the same day.

The e-SCM went live in July. Through this system, facilities, supply chain partners, USAID, manufacturers, and other stakeholders can access real-time data on Kenya Pharma inventory (via [www.kenyapharma.org](http://www.kenyapharma.org)); tenders and awards; SDP orders; delivery schedules; project reports, policies, and procedures; inventory at the district, provincial, and national levels; and clinics' contact information. The e-SCM's flexible design means it can be adapted to meet project needs as they evolve.

Management Sciences for Health publishes monthly treatment data on behalf of the Kenyan government. Kenya Pharma sends its report on the 12th of each month, with data on the number of patients in each region, consumption of each product, stocks at each SDP, and inventory at the central warehouse. By including data from all programs, the government knows how many months of stock are on hand.

### The Personal Touch

"Most of the other suppliers, we have never even seen them. We only know them by e-mail or phone. With Kenya Pharma, they normally visit once a month to see if everything is well. That is unique."

— Hillary Omala,  
clinic manager,  
Tabitha Health Centre, Kibera, Nairobi



PHOTO: KENYA PHARMA

Accurate reporting by SDPs helps to avert shortages of critical ARVs. "We used to have shortages. But, we don't anymore because we coordinate very closely on sending our monthly reports," said Mureithi Aruja, health pharmacist at Nakura Rift Valley Provincial General Hospital.

## SECTION VI. LOOKING AHEAD

Market forces have moved Kenya Pharma to a position of growing responsibility for PEPFAR's work in Kenya and to the country as a whole. PEPFAR and the Kenyan government have increasingly defined the project's objective as supplying a wider spectrum of commodities to the general HIV/AIDS-affected population. However, the unpredictable environment poses challenges in reaching PEPFAR and government targets while fulfilling immediate unexpected needs.

To meet these challenges going forward, the project will maintain an infrastructure that is supple enough to absorb constant change. It will necessitate creative thinking to access adequate supplies, given the limited number of international manufacturers, changing foreign exchange rates, a desire to encourage local producers, and the need to accelerate a QA process upon which payment, storage, and delivery depend.

This will require:

- Introducing higher levels of communication with all partners
- Expanding information-sharing through the e-SCM and other means
- Refining real-time data collection and its use for projecting procurement needs
- Recognizing the need for constant reappraisal of operational processes and infrastructure
- Continuing to look for cost-effective ways to achieve results
- Accelerating the lead time for local manufacturers, anticipating delays, and building them into project timelines when possible
- Creating a greater level of understanding of PEPFAR policies in Kenya
- Managing changes required by the new WHO treatment guidelines

Although work-planning for Year 2 will not occur until August, Kenya Pharma already has plans for meeting some of these objectives. They include:

*Procurement.* Project staff will travel to India to hear manufacturers' feedback on working with Pharma, discuss ways of ensuring adherence to deadlines, and to understand mutual challenges and operational processes.

*Shipment.* Once the supply chain is stable, the project will consider sea shipments. This could reduce shipping costs as much as 40 percent.

*Stocks.* Staff will give manufacturers a longer lead time by ordering further in advance of needs and will increase order quantities. Both will help stabilize stocks to respond to changing market demands.

*Quality assurance.* Because the project has a database of USAID-approved manufacturers' performance, the amount of testing can be reduced, saving time and money. Staff will also look at expanding the number of WHO-prequalified laboratories it

uses by looking at laboratories in South Africa and other countries, and working to help local manufacturers meet required standards.

*Delivery.* Staff will continue to refine the load consolidation process.

Kenya Pharma has built a strong, flexible, and responsive foundation. The next year will bring more opportunities to build on that foundation by working in partnership with the government and the wider Kenyan AIDS community to accomplish these important tasks.

## ANNEX A. DETAILED PERFORMANCE TABLE

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By	Performance Trend							Annual Comments/ Remarks	
			Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)		
<b>Project Objective: PEPFAR Commodity Supply Chain Strengthened</b>											
1	Effectiveness of supply chain (SN#1)	Process within supply chain	Forecasting								Will be done during the next reporting period and will be incorporated when conducting customer satisfaction survey in September/October 2010.
			Procurement								
			Ordering								
			QA								
			Shipment								
			Delivery								
			Storage								
<b>Total</b>											
<b>Project Intermediate Result 1: Overall management of the PEPFAR commodity supply chain strengthened</b>											
2	Functionality of e-SCM (SN#1)	Type of User	SDPs								The e-SCM system is now ready for deployment to users. Feedback on its usefulness and ease of use will be collected in Year 2.
			Kenya Pharma staff								
			Suppliers								
			Other stakeholders								
			Public								
		<b>Total</b>									
Ease of use											
Usefulness											
<b>Sub-PIR 1.1: Ability to monitor and report on entire PEPFAR supply chain strengthened</b>											
3	Percent of ad hoc requests responded to in a timely manner (SN#3)	N/A		100	100	100	100	100	99	99.75	All requests from USAID, NASCOP, KEMSA, and SDPs were responded to in a timely manner.
<b>Sub-PIR 1.2: Stakeholder and partner collaboration (U.S. donors, foundations, GOK, private sector, MEDS, KEMSA) strengthened</b>											
4	Number of opportunities for	Procurements	Procurements	3		3	5	3	3	14	Collaboration with KEMSA on the
			Forecasting								

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By	Performance Trend								Annual Comments/ Remarks
			Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)		
	collaboration identified by project staff (SN#4)		QA	1		1	1		3	5	transfer of stocks to and from KP; NASCOP on commodity security; DHL and Phillips on delivery model. Others included PPB, MEDS, NQCL, MSH, and Clinton Foundation.
			Logistics	3		3	3	1	2	9	
			<b>Total</b>	<b>7</b>		<b>7</b>	<b>9</b>	<b>4</b>	<b>8</b>	<b>28</b>	
5	Number of new pharmaceuticals registered with the USFDA/ Kenyan government that result in cost and treatment benefits (SN#4)	N/A		0		0	1	2	3	6	During the reporting period, four products were approved, two were tentatively approved by USFDA, and one was registered with PPB.
6	Number of meetings of relevant task forces and working groups that KP actively participates in (SN#4)	Type of task forces and working groups	Procurements						4	6	These included monthly commodity security meetings and the national forecasting and quantification of HIV/AIDS commodities exercise coordinated by NASCOP. Other meetings included OI list review,
			Forecasting	1		1	0	1			

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks	
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)		
			QA	0		0			2	2	PMTCT, and a logistic design workshop for harmonization of reporting tools.	
			Logistics	0		0	3	3	2	8		
			<b>Total</b>	<b>1</b>		<b>1</b>	<b>3</b>	<b>4</b>	<b>4</b>	<b>16</b>		
<b>Sub-PIR 1.3: Capacity of local organizations and staff working along the commodity supply chain improved</b>												
7	Number of training sessions delivered to all field agents (N/A)	Location	Nairobi/Central								The field team had three training sessions, all of which were done centrally but in different venues/locations.	
			Western/Nyanza									
			Coast, Eastern, and Northeast									
			Rift Valley									
			<b>Total</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>0</b>	<b>1</b>	<b>1</b>	<b>3</b>		
8	Number of tools shared with local organizations (N/A)	Type of tool	Forecasting	1			1			1	Product quality complaint forms shared with KP field agents. Storage and inventory assessment tools shared with KP field staff. KP will not be sharing new tools with SDPs because NASCOP will be developing harmonized tools for use across the national program. This indicator will be dropped.	
			QA	0					1	1		
			Reporting	0			1			1		
			Other					1	1	2		
			<b>Total</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>2</b>	<b>5</b>		
		Type of organizations	SDPs	1			2	1	2	5		
			Kenya Pharma	0	0			0		0		
			MOH/SDP	0			2	1		3		
			Other	0		0	0	0	1	1		
			<b>Total</b>	<b>1</b>	<b>0</b>	<b>0</b>	<b>2</b>	<b>1</b>	<b>1</b>	<b>4</b>		
<b>Sub-PIR 1.4: Customer service improved to service delivery points (Move to IR 1)</b>												
9	Number of complaints	Types of complaints	Quality issues	3	N/A	3	1	2	3	9	The majority were concerns and	
			Delivery/logistics	3	N/A	3	3	5	4	15		

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By	Performance Trend							Annual Comments/ Remarks	
			Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)		
	received from SDPs (N/A)		Public relations/customer care	1	N/A	1			2	3	queries regarding order management processes and KP product catalogue. Five concerns were about the similarity in packaging of
			Other (specify)		N/A			1	1	2	
			<b>Total</b>	<b>7</b>	<b>N/A</b>	<b>4</b>	<b>3</b>	<b>6</b>	<b>10</b>	<b>23</b>	
		Location	Nairobi/Central		N/A	1	1	1	2	5	
			Western/Nyanza		N/A		1	3	4	8	
			Coast, Eastern, Northeast		N/A		1	1	2	4	
			Rift Valley		N/A			1	2	3	

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
			<b>Total</b>		N/A	1	3	6	10	20	drug presentations from different manufacturers confusing the patients. One concern received regarding the side effects some patients are experiencing with a fixed-dose combination. On logistics, were mainly deliveries done but to the wrong SDP or did not get delivered to the final location. Query was received regarding some patients experiencing adverse drug effects with Cotrimoxazole 960 mg tablets. There were also concerns about regimens that needed to be updated in the ordering tools.
10	Quality rating on customer service	Location	Nairobi/Central	3.2						3.2	The survey is planned for September/October
			Western/ Nyanza	3.1						3.1	

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By	Performance Trend								Annual Comments/ Remarks
			Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)		
	satisfaction survey (N/A)		Coast, Eastern, Northeast	3.7						3.7	2010. Baseline indicated a rating 3.3 on a weighted scale (scale of 4.0).
			Rift Valley	3.1						3.1	
			<b>Total</b>	<b>3.3</b>						<b>3.3</b>	
<b>Project Intermediate Result 2: Compliant procurement processes enhanced</b>											
11	Number of compliant procurements completed (SN#1)	Type of commodity	ARVs (specify)	0		1	4	2	5	12	A total of 12 USAID approvals were received for ARV procurement; One OI procurement and another for dispensing envelopes were initiated. The new procurements will be evaluated and awarded in the next quarter.
			OIs (specify)	0			1			1	
			Other (specify)	0						0	
			<b>Total</b>	<b>0</b>		<b>1</b>	<b>5</b>	<b>2</b>	<b>5</b>	<b>13</b>	
<b>Sub-PIR 2.1: Quality of forecasting and quantification improved</b>											
12	Percentage of health facilities that experienced stock-outs in the last 12 months	Type of commodity	ARVs (specify)		0			46.2		46.2	These are baseline data (n=249). No further systematic data collection has been done since the baseline.
			OIs (specify)		0						
			Other (specify)		0						
			<b>Total</b>	<b>46.2</b>	<b>0</b>			<b>46.2</b>	<b>46.2</b>		
		Reason for stock-out	Delivery/logistics	24.1	0			24.1	24.1		
			Inaccurate documentation	8	0			8	8		
			Shortage/stock-out at supplier	2.8	0			2.8	2.8		
			Inaccurate quantification	2.4	0			2.4	2.4		
			Lack of advance notice	2.4	0			2.4	2.4		
			Not supplied at all	1.6	0			1.6	1.6		
Regimen change	0.8	0			0.8	0.8					
Others*	8	0			8	8					
<b>Total</b>	<b>44.2</b>	<b>0</b>			<b>44.2</b>	<b>44.2</b>					

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
		Location	Nairobi/Central	40	0			40		40	
			Western/Nyanza	60.5	0			60.5		60.5	
			Coast, Eastern, Northeastern	44.4	0			44.4		44.4	
			Rift Valley	32.7	0			32.7		32.7	
			<b>Total</b>	<b>46.2</b>	<b>0</b>			<b>46.2</b>		<b>46.2</b>	
13	Percentage accuracy of forecasting (SN#1)	Location	Nairobi/Central								We are in the process of reviewing the indicator because regimens are changing and requests from the Kenyan government are ad hoc and affect our stock levels.
			Western/Nyanza								
			Coast, Eastern, Northeastern								
			Rift Valley								
			<b>Total</b>								
N/A	Percent of sites that do accurate ordering		Nairobi/Central	63.2				78	97.8	87.9	
			Western/Nyanza	41.2				79	99.1	89.1	
			Coast, Eastern, Northeastern	52.6				77	99.8	88.4	
			Rift Valley	75				69	100	84.5	
			<b>Total</b>	<b>56.6</b>				<b>77</b>	<b>99.2</b>	<b>87.5</b>	
14	Numbers of site orders coming that are revised and changed centrally (N/A)	Reasons for revision	Buffering purposes		-	-	-	-	3 (1%)	3 (1%)	
			Less stock available		-	-	-	-	287 (63%)	287 (63%)	
			Out of stock/Less stock available		-	-	-	-	82 (18%)	82 (18%)	
			Out of stock/Substituted		-	-	-	-	24 (5%)	24 (5%)	
			Qty. Ordered -Too High		-	-	-	-	10 (2%)	10 (2%)	

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By	Performance Trend									
			Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	Annual Comments/Remarks		
		Qty. Ordered -too low		-	-	-	-	-	5 (1%)	5 (1%)		
			<b>Total</b>		-	-	-	-	-	<b>456 (91%)</b>		<b>456 (91%)</b>
		Location	Nairobi/Central	28 (36.8%)				32 (22%)	174 (32%)	27		
			Western/Nyanza	50 (59.3%)				21 (21%)	146 (31%)	26		
			Coast, Eastern, Northeastern	18 (47.4%)				19 (23%)	107 (26%)	24.5		
			Rift Valley	13 (25%)				6 (31%)	28 (5%)	18		
			<b>Total</b>	<b>109 (43.4%)</b>				<b>79 (23%)</b>	456 (90%)	56.5		
15	Number of emergency requisitions from sites (N/A)	Location	Nairobi/Central	24				5	4	9		
			Western/Nyanza	84				1	1	2		
			Coast, Eastern, Northeastern	13				1	2	3		
			Rift Valley	26				0	0	0		
			<b>Total</b>	<b>147</b>				<b>7</b>	<b>7</b>	<b>14</b>		
		Reason for requisition	Poor forecasting						7	7		
			Incomplete reports						-	-		
			Late reporting						-	-		
<b>Total</b>							<b>7</b>	<b>7</b>				
<b>Sub-PIR 2.2: Expansion of supplier base supported</b>												
16	Number of approved		ARVs (specify)	0		12	5	4	5	26	For OIs, sourcing done from the three	
			OIs (specify)	0		0	6		3	9		

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
	commodity sources identified (current and new) (SN#1, 4)		<b>Total</b>	<b>18</b>		<b>12</b>	<b>11</b>	<b>4</b>	<b>8</b>	<b>35</b>	USAID pre-approved suppliers. For the ARV commodities, KP continued to work with the previous awardees (Aurobindo Pharma Ltd., Hetero Drugs Ltd., Matrix Laboratories Ltd., and Strides Arcolab Ltd.)
17	Number of market research studies conducted (SN#1, 4)	Type of commodity	ARVs (specify)	4	1		4	2	1	8	Other searches were done for dispensing envelopes procured.
			Ols (specify)	1	1		1		1	3	
			Other (specify)		0				1	1	
			<b>Total</b>	<b>5</b>	<b>2</b>		<b>2</b>	<b>3</b>	<b>7</b>		
		Source	Studies		1					1	
			Internet		1				3	4	
			Other	5	0		5			5	
<b>Total</b>	<b>5</b>	<b>2</b>		<b>5</b>	<b>2</b>	<b>3</b>	<b>29</b>				
<b>Sub- PIR 2.3: Cost effectiveness (from a best value perspective) of procurements increased</b>											
18	Ratio of the median price paid by the country for each commodity in the last 12 months to the median international price (PEPFA R#)	Type of commodity	Stavudine/Lamivudine/Nevirapine 30/150/200 mg tablets	0.96	<1	0.96	0.76		0.76	0.827	In reference to the International Drug Price Indicator Guide, the analysis found that this ratio was less than one (<1). This means the project is paying less than the international price for a particular ARV
			Stavudine capsules 30 mg	0.6	<1		0.6		0.6	0.6	
			Efavirenz tablets 600 mg	0.38	<1		0.38		0.38	0.38	
			Lamivudine+Zidovudine tablets 150 mg/300 mg 60s	0.71	<1		0.71		0.73	0.72	
			Lamivudine+Zidovudine+Nevirapine tablets 150 mg/300 mg/200 mg 60s	0.87	<1		0.87		0.96	0.915	
			Nevirapine tablets 200 mg	0.73	<1		0.73		0.22	0.475	
			Tenofovir DF/Lamivudine tablets 300/300						0.73	0.73	

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
	H5.1.N/SN#3)		OIs	<1			<1	<1	<1	<1	medicine (single or fixed-dose combination).
			Other (specify)								
<b>Sub- PIR 2.4: Transparency of procurement process increased</b>											
19	Percentage of awards meeting transparency criteria: publication of the tender, sealed bids, neutral award committee, public bid opening, loss letters sent, data entered into e-SCM (N/A)	N/A		100	100	100	100	100	100	100	Transparency criteria was followed (e-mails sent to all bidders), although data has not been entered into the e-SCM. (It will be entered next quarter.)
<b>Sub- PIR 2.5: Supply of commodities assured</b>											
20	Number of PEPFAR commodities procured (Note:	Type of commodity	ARVs (specify)	1		1	6	5	8	20	Eight ARV and four OI commodities were procured in Quarter 4.
			OIs (specify)	0			43	2	4	49	
			Other (specify)	0					1	1	

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
	procurement must be deemed compliant with U.S. government and Kenyan procurement regulations to be counted.) (SN#1)		<b>Total</b>	1				7	13	20	
<b>Project Intermediate Result 3: QA of procured pharmaceuticals improved</b>											
21	Number of QA problems identified (SN#2)	Source of identification	Pre-shipment		N/A	0	0		0	0	QA received product complaints for pharmaceuticals procured and distributed by
			e-SCM		N/A	0	0		0	0	
			Partners		N/A	0	1		0	1	
			SDP	48	N/A	0	1	5	3	9	
			Other		N/A	0			1	1	

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By	Performance Trend							Annual Totals (Year 1)	Annual Comments/ Remarks
			Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4			
		Total	48	N/A	0	2	5	4	11	MEDS. The same were forwarded to MEDS for corrective action. Query was received from NASCOP on a particular batch number that was not received into KP warehouses during the stock transfer from MEDS. There was concern about the order management process and request for G4S account for submitting orders by SDPs.	
		Type of QA problem									
		Product	7	N/A	0	0	1	1	2	In one case, a product did not comply with the dissolution parameter. Concerns were raised twice about similarity in packaging. One patient complained of experiencing palpitations and vomiting. Patients experienced	
		Packaging	7	N/A	0	0	3	2	5		
		Labeling	6	N/A			1	0	1		
		Storage and handling	21	N/A	0	0	0	0	0		

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By	Performance Trend							Annual Comments/ Remarks	
			Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)		
		Customer care	1	N/A	0	1		1	1	adverse effects with Cotrimoxazole 960 mg tablets.	
		Other (specify)	6	N/A	0	1		1	2		
		<b>Total</b>	<b>48</b>	<b>N/A</b>	<b>0</b>	<b>2</b>	<b>5</b>	<b>4</b>	<b>11</b>		
22	Percentage of QA problems resolved (SN#2)	Type of QA problem	Product	0	100	100	100		100	100	All the QA problems were addressed. Two problems from previous MEDS stock were reported to MEDS (as indicated in the product complaints register). G4S account number was provided to clients.
		Packaging and labeling	0	100				100	100		
		Storage and handling	0	100							
		Customer care	0	100		100			100		
		Other (specify)	0	100				100	100		
		<b>Total</b>	<b>0</b>	<b>100</b>		<b>100</b>		<b>100</b>	<b>100</b>		
<b>Sub-PIR 3.1: Document verification and validation processes improved</b>											
23	Percentage of procured commodities with complete documentation in our files (SN#2)	Type of certification	USFDA	100	100	100	100	100	100	100	All the procured commodities have complete documentation in our files
			PPB	100	100	100	100	100	100	100	
			<b>Total</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>	
		Type of commodity	ARVs (specify)	100	100	100	100	100	100	100	
			Ols (specify)	100	100	100	100	100	100	100	
			<b>Total</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>	<b>100</b>	
<b>Sub-PIR 3.2: QA processes during procurement improved</b>											
24	Percentage of commodities that passed QA tests during procurement	Type of commodity	ARVs (specify)	100	100		100	100	98	99.5	Almost all received commodities complied with the inspection parameters as per
			Ols (specify)	100	100			100	100	100	
			<b>Total</b>	<b>100</b>	<b>100</b>	<b>0</b>	<b>100</b>	<b>100</b>	<b>99</b>	<b>99.8</b>	
		Type of inspection	Pre-shipment	100	100	0	100	100	100	99.9	
			Post-shipment	100	100	0	100	100	98	99.8	

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks	
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)		
	process		<b>Total</b>	100	100	0	100	100	99	99.8	ISO 2859-1:1999. One OI product did not comply with the dissolution parameter. One ARV product did not comply with all the contract packaging requirements.	
<b>Sub-PIR 3.3: QA processes during storage and handling improved</b>												
25	Percent of randomly tested procured commodities that pass QA certifications (SN#1)	Type of commodity	ARVs (specify)	100	100				100	100	Of 40 batches of commodities sent to NQCL for analysis, 95.8% complied with all test parameters. Two batches of Fluconazole 200 mg tablets did not comply with the dissolution test parameter	
			Ols (specify)	100	100			75	100	99.7		
			<b>Total</b>	100	100			75	100	95.8		
		Location	Nairobi/Central									No post-distribution surveillance was conducted this reporting year.
			Western/Nyanza									
	Location	Coast, Eastern, Northeastern								Activity is re-planned for Year 2.		
		Rift Valley										
		<b>Total</b>										
	Percent of SDP site inspections passed (SN#1)	Location	Nairobi/Central								No inspection was conducted in Year 1 due to emerging issues,	
			Western/Nyanza									
Coast, Eastern, Northeastern												
Rift Valley												

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
			<b>Total</b>								circumstances, and budgetary constraints. This activity has been planned again; the indicator will be captured in Year 2.
<b>Project Intermediate Result 4: Efficiency and security of commodity storage and delivery improved</b>											
26	Percentage of deliveries made within agree-upon timeframe with SDPs (SN#1)	Location	Nairobi/Central	92.8	N/A	92.8	98.89	100	99.5	97.8	A total of 1,399 deliveries were made. Only 6.2% missed the 24-hour delivery schedule (during January and May, due to inaccessible roads and poor conditions).
			Western/Nyanza	82.2	N/A	82.2	100	93.55	97	97.5	
			Coast, Eastern, Northeastern	96.8	N/A	96.8	97.96	100	96.8	97.9	
			Rift Valley	87.5	N/A	87.5	97.44	100	90.2	93.8	
			<b>Total</b>	<b>89.8</b>	<b>N/A</b>	<b>89.9</b>	<b>98.6</b>	<b>98.4</b>	<b>95.88</b>	<b>95.7</b>	
27	Number of commodities received in central warehouse with scheduled timeframe (N/A)	Type of commodity	ARVs (specify)				1	2	6	9	All commodities were received into the central warehouse within the agreed-upon 48-hour timeframe.
			Ols (specify)				0		32	32	
			<b>Total</b>				<b>1</b>	<b>2</b>	<b>38</b>	<b>41</b>	
28	Effectiveness of SOPs in preventing commodity security issues	Type of commodity	ARVs (specify)		0						SOPS have decreased delivery delays, and prevented and managed security problems (e.g.,
			Ols (specify)		0						
			<b>Total</b>								
		Reason for security breach	Stock-out								
			Expiry								
		Losses									

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
			Other								stock-out, expiry and losses). Stakeholders clearly understand SOPs. Weighting of SOPs' effectiveness will be done next year.
<b>Sub-PIR 4.1: Traceability of commodities improved</b>											
29	Percent of internal traceability tests passed (N/A)	Type of commodity	ARVs (specify)		100						No data available yet. Connection to DHL's commodity-tracking system and the e-SCM will be done in Year 2.
			Ols (specify)		100						
			<b>Total</b>		<b>100</b>						
<b>Sub-PIR 4.2: Storage practices of commodities improved.</b>											
30	Number of commodities damaged during storage and handling (N/A)	Type of commodity	ARVs (specify)		0	0	0	0	0	0	Nine commodities were damaged due to poor handling during shipping and storage. Though no damage was reported at the central warehouse, 1,230 cartons were packaged using 3-ply instead of 5-ply cartons, per the purchasing contract.
			Ols (specify)		0	0	0	0	0	0	
			<b>Total</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	
		Reason for damage	Poor handling		0	0	0	0	0	0	
			Poor packaging		0	0	0	0	9	9	
			Insects and rodents		0	0	0	0	0	0	
			Extreme weather		0	0	0	0	0	0	
			Other (specify)		0	0	0	0	0	0	
		<b>Total</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>9</b>	<b>9</b>		
		Location	Nairobi/Central		0	0	0	0	0	0	
			Western/Nyanza		0	0	0	0	0	0	
Coast, Eastern, Northeastern			0	0	0	0	0	0			
Rift Valley			0	0	0	0	0	0			
Central warehouse			0	0	0	0	9	9			
<b>Total</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>9</b>	<b>9</b>				
31	Percent of	Storage	Space	61				61		61	These were the

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
	storage facilities that meet storage needs (N/A)	needs	Security and safety	88.8				88.8		88.8	baseline data. This indicator should be dropped or reviewed. KP is not fully controlling or addressing issues such as space, equipment, security and safety, and infrastructure investment (e.g., ventilation, lighting, stacking).
			Equipment (e.g., cold storage)	68				68		68	
			Ventilation	92.4				92.4		92.4	
			Cleanliness	77.6				77.6		77.6	
			Lighting	94.4				94.4		94.4	
			Stacking of cartons	22				22		22	
			Measures to prevent rodent and insect infestation	88				88		88	
			<b>Total</b>	<b>74</b>				<b>74</b>		<b>74</b>	
		Location	Nairobi/Central	74.4				74.4		74.4	
			Western/Nyanza	67.9				67.9		67.9	
			Coast, Eastern, Northeastern	73.1				73.1		73.1	
Rift Valley	80.8					80.8		80.8			
<b>Total</b>	<b>74</b>				<b>74</b>		<b>74</b>				
<b>Sub-PIR 4.3: Freight forwarding and delivery practices improved</b>											
32	Average time to clear stock through customs (N/A)	Reason for delay	Inaccurate documentation		N/A		1		0	0.333	On average, it took 2.3 days for commodities to clear customs, which was acceptable. The previous delay was caused because the importer's pin number had not been activated with customs.
			Lack of advance notice		N/A		0		0	0	
			Other	1	N/A		0	1	0	0.333	
			<b>Total</b>	<b>1</b>	<b>N/A</b>		<b>1</b>	<b>1</b>	<b>3</b>	<b>1.7</b>	
33	Average delivery time to SDPs	Location	Nairobi/Central	0.5	2	0.5	1	0.6	1.02	0.78	On average, it took 1.15 days to deliver commodities to the facilities. The slight
			Western/Nyanza	1	2	1	1	1	1.21	1.06	
			Coast, Eastern, Northeastern	1	2	1	2	1	1.13	1.28	
			Rift Valley	1	2	1	2	1	1.24	1.31	

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
			<b>Total</b>	<b>0.88</b>	<b>2</b>	<b>0.88</b>	<b>1.5</b>	<b>0.9</b>	<b>1.15</b>	<b>1.11</b>	increase in Qtr. 4 was due to wet weather conditions that made some roads inaccessible.
<b>Sub-PIR 4.4: Inventory management increased (shipping and delivery)</b>											
34	Number of commodities lost during shipping and delivery (N/A)	Reason for loss	Theft	0	0	0	0	0	0	0	75 units of TDF/3TC were lost during clearing at the airport.
			Spoilage	0	0	0	0	0	0	0	
			Destruction	0	0	0	0	0	0	0	
			Other	0	0	0	0	0	75	75	
			<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>75</b>	
		Location	Sea	0	0	0	0	0	0	0	
			Central warehouse	0	0	0	0	0	0	0	
			In transit	0	0	0	0	0	75	75	
			SDPs	0	0	0	0	0	0	0	
			<b>Total</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>75</b>	
35	Frequency of commodity loss (N/A)	Reason for loss	Theft	13 (61.9%)	N/A			0	0	0	Only 75 units of TDF/3TC were lost while going through customs (because they were not palletized).
			Spoilage	3 (14.3%)	N/A			0	0	0	
			Destruction	1 (4.8%)	N/A			0	0	0	
			Expiry	3 (14.3%)	N/A			0	0	0	
			Breakages	3 (14.3%)	N/A			0	0	0	
			Theft and breakages	3 (14.3%)	N/A			0	0	0	
			Don't know	3 (14.3%)	N/A			0	0	0	
			Other		N/A			0	1	1	

No.	Indicator Source/ Award Fee Criteria (SN#)	Disaggregated By		Performance Trend							Annual Comments/ Remarks
				Baseline	Target	Quarter 1	Quarter 2	Quarter 3	Quarter 4	Annual Totals (Year 1)	
			<b>Total</b>	<b>21 (100%)</b>	N/A	<b>0</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>1</b>	
		Location	Nairobi/Central	2	N/A	0	0	0	0	0	
			Western/Nyanza	10	N/A	0	0	0	0	0	
			Coast, Eastern, Northeastern	3	N/A	0	0	0	0	0	
			Rift Valley	4	N/A	0	0	0	0	0	
			<b>Total</b>	<b>19</b>	N/A	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
36	Percent of sites complying with inventory management SOPs (N/A)	Location	Nairobi/Central		100						All sites are complying with Ministry of Health storage and inventory management procedures. There has been no formal measurement because the SDPs are not using KP procedures. Therefore, this indicator should be dropped.
			Western/Nyanza		100						
			Coast, Eastern, Northeastern		100						
			Rift Valley		100						
			<b>Total</b>		<b>100</b>						

## ANNEX B. STOCK, DISTRIBUTION, EXPIRY, AND BRANDING AND MARKING REPORTS

### Stock Report (as of July 5, 2010)

No	Item/Commodity Description	Unit Stock Quantity Balance (By End of Year 1)	Expiration Date
1	Acyclovir 200 mg tablets 30s	9,286	12/1/2012
2	Amoxicillin 500 mg capsules 500s	15,643	2/1/2013
3	Amoxicillin/clavulanate 625 mg tablets 14s	13,300	3/1/2012
4	Amphotericin B 50 mg injection 1s	9,103	3/1/2012
5	Azithromycin 200 mg/5 ml powder 15 ml	2,247	10/1/2011
6	Cefuroxime 125 mg/5 ml powder 70 ml	4,190	7/1/2011
7	Cefuroxime 250 mg tablets 10s	4,390	7/1/2011
8	Chlorpheniramine maleate 4 mg tablets 1,000s	6,958	11/1/2014
9	Chlorpheniramine 2 mg/5 ml syrup 100 ml	22,681	1/1/2013
10	Clotrimazole cream 20 mg	2,990	11/1/2012
11	Cotrimoxazole 240 mg/5 ml suspension 100 ml	39,339	12/1/2012
12	Cotrimoxazole tablets 960 mg 500s	23,773	2/1/2013
13	Dapsone 100 mg tablets 1,000s	3,823	12/1/2014
14	Doxycycline 100 mg capsules 100s	1,750	6/1/2012
15	Efavirenz 600 mg tablets 30s	35,808	2/1/2012
16	Efavirenz 600 mg tablets 30s	2	1/1/2012
17	Erythromycin 500 mg tablets 100s	3,578	1/1/2013
18	Fluconazole 200 mg tablets 100s	25,525	6/1/2012
19	Hydrocortisone 15 mg cream	312	1/1/2013
20	Ibuprofen 400 mg tablets 500s	2,784	1/1/2013
21	Indinavir capsules 400 mg 180s	179	1/1/2011
22	Ketoconazole 200 mg tablets 30s	4,842	10/1/2012
23	Lamivudine tablets 150 mg 60s	62,387	6/1/2011
24	Lamivudine tablets 150 mg 60s	167	12/1/2010
25	Lamivudine/Zidovudine 150 mg/300 mg tablets	41,158	1/1/2012
26	Lamivudine/Zidovudine/Nevirapine 150/300/200 mg tablets	875	2/1/2012
27	Loperamide 2 mg capsules 1,000s	1,220	12/1/2012
28	Mebendazole 100 mg/ ml suspension 30 ml	122	1/1/2013
29	Multivitamin tablets 1,000s	111	12/1/2012
30	Nelfinavir tablets 250 mg 270s	54	5/1/2011
31	Nevirapine tablets 200 mg 60s	40	5/1/2011
32	Nevirapine tablets 200 mg 60s	47,531	1/1/2013
33	Ors 500 ml sachets (WHO formula) 100s	244	12/1/2012
34	Paracetamol 500 mg tablets 1,000s	60	12/1/2014
35	Prednisolone 5 mg tablets 100s	3,000	10/1/2014
36	Pyridoxine 50 mg tablets 100s	52,269	12/1/2013
37	Saquinavir capsules 200 mg 270s	148	6/1/2012
38	Stavudine capsules 30 mg 60s	13	3/1/2011
39	Stavudine capsules 30 mg 60s	53,083	11/1/2011
40	Stavudine/Lamivudine/Nevirapine 30 mg/150 mg/200 mg	224,272	5/1/2011
41	Tenofovir/Lamivudine tablets 300 mg 30s	411,593	2/1/2012
42	Zidovudine tablets 300 mg 60s	3,958	5/1/2011

## Distribution Report, August 6, 2009 - July 5, 2010

No	Item/Commodity Description	Unit Quantity Delivered to SDPs
1	Abacavir oral solution 240 ml	30
2	Acyclovir tablets 200 mg 30s	19,984
3	Amoxicillin 125 mg/5 ml powder 100 ml	10,800
4	Amoxicillin 500 mg capsules 500s	2,377
5	Amoxicillin/Clavulanate 625 mg tablets 14s	229
6	Amphotericin B 50 mg injection 1s	1,168
7	Azithromycin 200 mg/5 ml powder 15 ml	1,271
8	Cefuroxime 125 mg/5 ml powder 70 ml	160
9	Cefuroxime 250 mg tablets 10s	460
10	Chlorpheniramine Maleate 4 mg tablets 1,000s	580
11	Chlorpheniramine 2 mg/5 ml syrup 100 ml	3,656
12	Ciprofloxacin 500 mg tablets 100s	7,917
13	Clotrimazole cream 20 mg	3,925
14	Cloxacillin 250 mg capsules 1,000s	398
15	Cotrimoxazole (Sulfran-DS) tablets 960 mg 500s	12,606
16	Cotrimoxazole 240 mg/5 ml suspension 100 ml	137,118
17	Cotrimoxazole tablets 960 mg 500s	138,524
18	Dapsone 100 mg tablets 1,000s	759
19	Didanosine tablets 100 mg 60s	43
20	Didanosine tablets 200 mg 60s	8,021
21	Didanosine tablets 25 mg 60s	4,769
22	Efavirenz 600 mg tablets 30s	211,596
23	Efavirenz oral solution 180 ml	7,985
24	Efavirenz tablets 200 mg 90s	140
25	Efavirenz tablets 50 mg 30s	100
26	Efavirenz tablets 600 mg 30s	222,880
27	Erythromycin 500 mg tablets 100s	467
28	Fluconazole 200 mg tablets 100s	24,393
29	Hydrocortisone 15 mg cream	3,000
30	Hyoscine butyl bromide injection, 20 mg/ml ampoules 5s	375
31	Ibuprofen 100 mg/5 ml syrup 100 ml	4,450
32	Ibuprofen 200 mg tablets 1,000s	30
33	Ibuprofen 400 mg tablets 500s	1,098
34	Indinavir capsules 400 mg 180s	117
35	Ketoconazole 200 mg tablets 30s	314
36	Lamivudine tablets 150 mg 60s	404,756
37	Lamivudine/Zidovudine 150 mg /300 mg tablets 60s	433,812
38	Lamivudine/Zidovudine/Nevirapine 150/300/200 mg tablets 60s	102,593

No	Item/Commodity Description	Unit Quantity Delivered to SDPs
39	Loperamide 2 mg capsules 1,000s	1
40	Mebendazole 100 mg/ml suspension 30 ml	3,852
41	Metronidazole 200 mg tablets 1,000s	459
42	Metronidazole 200 mg/5 ml suspension 100 ml	1,848
43	Metronidazole 400 mg tablets 1,000s	154
44	Multivitamin tablets 1,000s	4,658
45	Multivitamin syrup 100 ml	45,781
46	Nelfinavir tablets 250 mg 270s	33
47	Nevirapine tablets 200 mg 60s	433,491
48	Nystatin oral drops 30 ml	13
49	Ors 500 ml sachets (WHO formula) 100s	741
50	Paracetamol 120 mg/5 ml suspension 100 ml	9,532
51	Paracetamol tablets 500 mg 1,000s	2,398
52	Pyridoxine 50 mg tablets 100s	2,687
53	Saquinavir capsules 200 mg 270s	260
54	Stavudine capsules 15 mg 60s	100
55	Stavudine capsules 20 mg 60s	100
56	Stavudine capsules 30 mg 60s	199,914
57	Stavudine/Lamivudine/Nevirapine 30 mg/150 mg/200 mg tablets 60s	27,315

## Expiry Report (at SDPs)

Facility	ARV Supply	Drug	Quantity (Packs)	Weight, per Pack (kg)	Weight (kg)	Sponsor	Expiration Date
Gertrudes Hospital	KP/MEDS	Didanosine 25 mg	105	0.18	18.90	PEPFAR	Feb-10
Gertrudes Hospital	KP/MEDS	Didanosine 25 mg	28	0.18	5.04	PEPFAR	Feb-10
Gertrudes Hospital	KP/MEDS	Didanosine 200 mg	8	0.18	1.44	PEPFAR	Feb-10
Khunyangu AMPATH clinic	KP/MEDS	Stavudine 30 mg capsules	434	0.04	17.36	PEPFAR	Jan-10
Khunyangu AMPATH clinic	KP/MEDS	EFV 600 mg	330	0.08	26.40	PEPFAR	Feb-10
Khunyangu AMPATH clinic	KP/MEDS	AZT 300 mg	480	0.04	19.20	PEPFAR	Mar-10
Turbo Health Centre	KP/MEDS	AZT 300 mg	57	0.04	2.28	PEPFAR	Mar-10
Kapsabet District Hospital	KP/MEDS	AZT/3TC	23	0.08	1.84	PEPFAR	May-10
Kericho District Hospital	KP/MEDS	Stavudine	3	0.04	0.12	PEPFAR	Mar-10
KapKatet District Hospital	KP/MEDS	Stavudine	12	0.04	0.48	PEPFAR	Mar-10
Our Lady of Lourdes Mwea Mission	KP/MEDS	Stavudine 30 mg capsules	10	0.04	0.40	PEPFAR	Feb-10
Kendu Adventist	KP/MEDS	AZT	16	0.04	0.64	PEPFAR	Jan-10
		Stavudine	15	0.04	0.60	PEPFAR	Feb-10
Nyumbani Children's Home	KP/MEDS	EFV 180ml	38	0.26	9.88	PEPFAR	Apr-10
		Didanosine 200 mg tablets 60s	161	0.18	28.98	PEPFAR	Mar-10
		ddl 250 mg tablets 60s	18	0.18	3.24	PEPFAR	Mar-10
Akala Health Centre	KP/MEDS	Stavudine 30 mg capsules	81	0.04	3.24	PEPFAR	Feb-10
Akala Health Centre	KP/MEDS	EFV 600 mg	119	0.08	9.52	PEPFAR	Apr-10
St Elizabeth, Lwak	KP/MEDS	AZT 300 mg	45	0.04	1.80	PEPFAR	Mar-10
Coptic Hospital	KP/MEDS	Stavudine 30 mg capsules	192	0.04	7.68	PEPFAR	Feb-10
Coptic Hospital	KP/MEDS	Didanosine 25 mg capsules	23	0.18	4.14	PEPFAR	Feb-10
Coptic Hospital	KP/MEDS	Didanosine 200 mg tablets	170	0.18	30.60	PEPFAR	Feb-10
Coptic Hospital	KP/MEDS	Triomune 30 mg tablets	1920	0.08	153.60	PEPFAR	Feb-10
Dream Centre	KP/MEDS	Didanosine 200 mg	9	0.18	1.62	PEPFAR	Jan-10
Busia AMPATH clinic	KP/MEDS	Didanosine 200 mg	80	0.18	14.40	PEPFAR	Feb-10

Facility	ARV Supply	Drug	Quantity (Packs)	Weight, per Pack (kg)	Weight (kg)	Sponsor	Expiration Date
Busia AMPATH clinic	KP/MEDS	EFV 600 mg	180	0.08	14.40	PEPFAR	Feb-10
Muranga District Hospital	Dual	EFV 30 mg/ml	140	0.26	36.40	PEPFAR	Feb-10
Thika District Hospital	Dual	EFV syrup 30 mg/ml	53	0.26	13.78	PEPFAR	Feb-10
New Nyanza General Hospital	KP/MEDS	Saquinavir	27	0.48	12.96	PEPFAR	Mar-10
<b>Subtotal</b>					<b>440.94</b>		
Khunyangu AMPATH clinic	KP/MEDS	Stavudine 15 mg	25		0	CHAI	Jan-10
Akala Health Centre	KP/MEDS	3TC oral solution	118		0	CHAI	Feb-10
Coptic Hospital	KP/MEDS	Kaletra syrup	45		0	CHAI	Feb-10
Thika District Hospital	Dual	Didanosine 25 mg tablets	85	0.18	15.30	CHAI	Feb-10
Thika District Hospital	Dual	Didanosine 50 mg tablets	70	0.18	12.60	CHAI	Feb-10
Thika District Hospital	Dual	Didanosine 200 mg tablets	48	0.18	8.64	CHAI	Mar-10
Thika District Hospital	Dual	Didanosine 250 mg tablets	76		0	CHAI	Feb-10
Thika District Hospital	Dual	Nevirapine syrup 10 mg	158		0	CHAI	Dec-09
Karatina District Hospital	Dual	Didanosine 50 mg tablets	40	0.18	7.20	CHAI	Mar-10
Muranga District Hospital	Dual	Didanosine 25 mg	57	0.18	10.26	CHAI	Feb-10
Muranga District Hospital	Dual	Didanosine 100 mg	41	0.18	7.38	CHAI	Feb-10
Muranga District Hospital	Dual	Didanosine 200 mg	24	0.18	4.32	CHAI	Feb-10
Friends, Lugulu Mission Hospital	Dual	NVP syrup	69		0	CHAI	Dec-09
PCEA Kikuyu Hospital	Dual	Abacavir 300 mg	36		0	CHAI	Mar-10
Machakos District Hospital	Dual	Abacavir 300 mg	21		0	CHAI	Feb-10
		Didanosine 25 mg	25	0.04	1	CHAI	Feb-10
		Didanosine 100 mg	5	0.04	0.20	CHAI	Feb-10
		Didanosine 200 mg	27	0.04	1.08	CHAI	Feb-10
		Efavirenz syrup	15		0	CHAI	Apr-10
		Kaletra syrup	6		0	CHAI	Dec-09
		AZT 300 mg tablets	3	0.04	0.12	To Determine	Mar-10
New Nyanza General Hospital	Dual	Didanosine 200 mg	47	0.18	8.46	CHAI	Mar-10
		EFV 600 mg	25	0.08	2	To Determine	Apr-10

Facility	ARV Supply	Drug	Quantity (Packs)	Weight, per Pack (kg)	Weight (kg)	Sponsor	Expiration Date
Kitale District Hospital	Dual	Stavudine 30 mg	56	0.04	2.24	To Determine	Feb-10
Karatina District Hospital	Dual	Stavudine 20 mg	87		0	KEMSA	Feb-10
Thika District Hospital	Dual	Stavudine 20 mg capsules	120		0	KEMSA	Mar-10
PCEA Kikuyu Hospital	Dual	Stavudine 20 mg tablets	123		0	KEMSA	Feb-10
PCEA Kikuyu Hospital	Dual	Stavudine 30 mg tablets	215	0.04	8.60	To Determine	Feb-10
Mois Bridge Health Centre	KEMSA	Stavudine 20 mg	4		0	KEMSA	Mar-10
Mois Bridge Health Centre	KEMSA	EFV 50 mg	1		0	KEMSA	Feb-10
Kyangi SDH	KEMSA	Zidolam	17		0	KEMSA	Feb-10
Kiria-ni Mission Hospital	KEMSA	EFV 200 mg	300		0	KEMSA	Apr-10
Macalder District Hospital	KEMSA	EFV 200 mg	600		0	KEMSA	Apr-10
Gongoni Health Centre	KEMSA	3TC 240 ml	11		0	KEMSA	Jan-10
Gongoni Health Centre	KEMSA	NVP 240 ml	1		0	KEMSA	Dec-09
<b>Subtotal</b>					<b>89.40</b>		
<b>Total</b>					<b>530.34</b>		

## Expiry Report (Central Warehouse)

Reference Number	Product	Bin Quantity	Batch Number	Expiration Date	Computer Quantity	Physical Quantity	Variance Quantity
BMS-DIDA-191	Didanosine tablets 25 mg		0089	1-Feb-2010	50	40	-10
			0094	1-Mar-2010	21	21	0
		<b>71</b>			<b>71</b>	<b>61</b>	<b>-10</b>
BMS-DIDA-194	Didanosine tablets 200 mg		0057	1-Feb-2010	4	9	5
			0059	1-Mar-2010	1,712	1,712	0
		<b>1,716</b>			<b>1,716</b>	<b>1,721</b>	<b>5</b>
MSD-EFAV-221	Efavirenz oral solution		NG50470	1-Apr-2010	116	116	0
			NH06530	1-Apr-2010	1,550	1,550	0
			NH16110	1-Apr-2010	1,758	1,758	0
			NH18730	1-Apr-2010	1,692	1,692	0
		<b>5,116</b>			<b>5,116</b>	<b>5,116</b>	<b>0</b>
STR-STAV-642	Stavudine 30 mg capsules, 60s		7205400	1-Feb-2010	0	4	4
			7205499	1-Feb-2010	143	146	3
			7205500	1-Feb-2010	3,881	3,881	0
			7205617	1-Feb-2010	11,166	11,166	0
			7205618	1-Feb-2010	16,177	16,177	0
			7205619	1-Feb-2010	2,282	2,282	0
					<b>33,649</b>	<b>33,652</b>	<b>3</b>

## Branding and Marking

Material	USAID/ Kenya Pharma Sub-brand	Kenya Pharma Name Only	PEPFAR Marking	No Branding	Notes
<b>Administrative Items</b>					
Stationary (e.g., letterhead, envelopes, faxes coversheets)	X		X		The project will use Chemonics letterhead when it enters into a contractual relationship with a third party (e.g., hiring staff and signing leases) per ADS 320.3.1.5.
Business cards		X			Per ADS 320.3.1.6, the project will not put the USAID brand identity on its business cards. The project also will not use the PEPFAR identity on its cards.
Office signs	X		X		
Deliverables (e.g., reports)	X		X		
Tender documents and advertisements	X		X		
Project vehicles	X		X		
<b>Technical and Promotional Materials</b>					
Project Web site	X		X		
Training manuals and materials	X		X		
PowerPoint presentations	X		X		
Newsletter/ e-bulletin	X		X		
Success stories	X		X		
<b>Commodities and Materials Associated with Shipments</b>					
Waybill				X	As a security measure, the waybill will contain only the name of the shipper, usually DHL.
Address labels	X		X		
Boxes/cartons	X		X		Cartons of commodities will be marked with PEPFAR co-branded stickers when they arrive at the Kenya Pharma warehouse. To reduce costs associated with branding, the project will use black-and-white stickers and place them on only one side of the box.
Shipments	X		X		Boxes for small shipments will be wrapped in brown paper and sealed with black-and-white tape co-branded with the PEPFAR logo. Large shipments will be shrink-wrapped, and labeled with black-and-white stickers.
Warehouse signs	X		X		

## **ANNEX C. ANNUAL MARKET RESEARCH REPORT, JULY 2009- JULY 2010**

Over the course of the year, Kenya Pharma worked to establish procurement and other supply chain systems with a focus on establishing ARV stock-levels needed to reach the PEPFAR target populations. The project also worked to establish relationships with suppliers and tailor its systems to appeal to manufacturers and streamline the procurement process for maximum time and cost efficiencies.

The change in the WHO-recommended guidelines regarding Stavudine significantly affected our procurements and planning. Immediately after the announcement, we saw a shift in regimen trends that was not properly controlled. Kenya Pharma at first adapted its plans to the guidelines proposed by the Kenyan government — using TDF as a primary first-line regimen — but shortly thereafter identified that most sites shifted to AZT-based regimens. Again, the team adapted to the realities on the ground and worked hard to procure the necessary commodities as quickly as possible. As a consequence of the new WHO guideline recommendations, regimen preferences shifted globally, and manufacturers were quickly overloaded with orders, resulting in long lead times.

General trends in commodity pricing over the year led to cost savings, which was positive for the project. Kenya Pharma has noted that pricing for Nevirapine and Lamivudine/Zidovudine has been relatively stable, whereas pricing for Stavudine/Lamivudine/Zidovudine has decreased. Efavirenz prices have been significantly reduced compared with the published ceiling prices reported by the Clinton Foundation. Furthermore, the project believes the revised guidelines for ART treatment will lower the cost of AZT-based and TDF-based triple fixed-dose combinations because new suppliers will come into the market, whereas previously there was only one eligible supplier.

### **Summary of ARV Procurements**

Over the course of the first year of implementation, Kenya Pharma had eight different procurements for ARVs. The table below outlines the quantities ordered and prices at which the commodities were contracted. Please note that while cost was an important factor in the evaluation process, Kenya Pharma selected proposals based on a best-value concept, which considered past performance and the most advantageous delivery schedule.

RFP Ref #	Item	Pack size	Quantity	Unit Price Awarded (USD)	KP Median Unit Price (USD)	International Median Price (USD)	Ratio
KPP/01/09	Stavudine/Lamivudine/Nevirapine 30/150/200 mg tablets	60	300,000	6.25	6.25	8.10	0.77
KPP/02/09	Stavudine Capsules 30 mg	60	100,000	1.40	1.40	2.33	0.60
KPP/03/09	Efavirenz Tablets 600 mg	30	120,000	5.03	5.03	12.44	0.40
	Lamivudine+Zidovudine tablets 150 mg/300 mg 60s	60	70,000	8.61	8.61	11.73	0.73
KPP/04/09	Efavirenz Tablets 600 mg	30	100,000	4.50	4.77	12.44	0.38
	Lamivudine+Zidovudine tablets 150 mg/300 mg	60	84,000	8.05	8.33	11.73	0.71
	Stavudine/Lamivudine/Nevirapine 30/150/200 mg tablets	60	909,000	5.75	6.00	7.24	0.83
	Lamivudine+Zidovudine+Nevirapine Tablets 150 mg/300 mg/200 mg 60s	60	73,470	11.26	11.26	11.73	0.96
KPP/05/09	OI Drugs	List in OI procurements section					
KPP/06/09	Nevirapine Tablets 200 mg	60	80,000	3.00	11.26	12.92	0.87
	Lamivudine+Zidovudine+Nevirapine tablets 150 mg/300 mg/200 mg 60s	60	120,000	11.26	11.26	11.73	0.96
KPP/01/10	Efavirenz Tablets 600 mg	30	350,000	4.36	4.63	12.58	0.37
	Lamivudine+Zidovudine tablets 150 mg/300 mg	60	75,000	8.96	8.54	11.82	0.72
	Nevirapine tablets 200 mg	60	400,000	2.59	2.80	5.99	0.47
	Lamivudine+Zidovudine+Nevirapine Tablets 150 mg/300 mg/200 mg 60s	60	250,000	11.25	11.26	17.85	0.63
	Tenofovir DF/Lamivudine tablets 300/300	30	900,000	9.75	9.75	12.34	0.79
KPP/02/10	Efavirenz tablets 600 mg	30	200,000	4.22	4.43	12.58	0.35
	Lamivudine+Zidovudine tablets 150 mg/300 mg	60	385,000	8.70	8.62	11.82	0.73
	Lamivudine+Zidovudine+Nevirapine tablets 150 mg/300 mg/200 mg 60s	60	130,000	11.35	11.30	17.85	0.63
	Lamivudine+Zidovudine+Nevirapine tablets 150 mg/300 mg/200 mg 60s	60	200,000	12.75	11.30	17.85	0.63
	Nevirapine tablets 200 mg 60s	60	650,000	2.52	2.66	5.99	0.44
	Tenofovir DF/Lamivudine tablets 300 mg/300 mg Tablets 30s	30	100,000	9.75	9.75	12.34	0.79
	Zidovudine Tablets 300 mg	60	200,000	7.15	7.15	11.20	0.64

The average ratio of the Kenya Pharma median unit price to the international median unit price was 0.68:1.00, showing that the project was able to obtain significant savings. The project also identified challenges with certain commodities during procurements. These lessons will need to be integrated into the timing of future procurement planning:

- *Efavirenz tablets (600 mg)*. One manufacturer noted difficulty in getting the active API to produce the item. As a result, Pharma canceled the award and found another manufacturer that manufactured both the product and the API. In the future, the evaluation committee must take note of the availability of the API and what kind of security the manufacturer has of obtaining it when needed.
- *Lamivudine+Zidovudine+Nevirapine tablets (150/300/200 mg)*. Only two manufacturers have the required approvals and registrations for this project, one of which is a very recent addition. Therefore, it is important to monitor lead times with manufacturers and factor longer times for production into the procurement planning.
- *Nevirapine tablets (200 mg)*. Similar to Efavirenz, one of the manufacturers awarded a contract to supply Nevirapine noted difficulty in obtaining the API. This resulted in production delays and late deliveries, which strained supply in the Kenya Pharma central warehouses and the ability to distribute ideal quantities to the SDPs. Such potential delays must be factored into procurement planning to avoid similar issues in the future.

### **Summary of OI Drug Procurements**

The Kenya Pharma project also procured drugs to address OIs. With an aim to strengthen capacity to produce the much-needed HIV commodities locally, the project procured according to qualifications that would permit suppliers' participation in the competition. Adding these suppliers to the pool of potential manufacturers resulted in an overall cost savings to the project because they were able to produce and deliver the commodities at reduced costs. However, working through local manufacturers created challenges, such as extended delivery times due to small batches, which in turn increased the strain on the project's quality assurance process to test a higher number of batches. The supply chain team worked over the year to identify methods of continuing to work through these companies while streamlining delivery times.

Item	Pack Size	Quantity	KP Median Unit Price (KES)	KP Median Unit Price (USD)	Median International Price (USD)	Ratio
Acyclovir 200 mg tablets	30	16,500	65	0.850	1.653	0.51
Amoxicillin 125 mg/5 ml powder, 100 ml	1	10,800	26	0.340	0.550	0.62
Amoxicillin/Clavulanate 625 mg tablets	14	13,308	182	2.379	3.674	0.65
Amoxicillin 250 mg capsules	1000	1,500	1225	16.013	24.200	0.66
Amoxicillin 500 mg capsules	500	18,000	1175	15.359	22.500	0.68
Amphotericin B 50 mg injection	1	60,000	395	5.166	6.440	0.80
Azithromycin 200 mg/5 ml powder, 15 ml	1	3,000	95	1.242	1.969	0.63
Cefuroxime 125 mg/5 ml Powder, 70 ml	1	4,200	148	1.935	3.339	0.58
Cefuroxime 250 mg tablets	10	5,000	150	1.961	2.767	0.71
Chlorpheniramine maleate Tabs 4mg	1000	7,500	75	0.980	4.200	0.23
Chlorpheniramine 2mg/5 ml Syrup, 100 ml	1	26,250	17	0.216	0.220	0.98
Ciprofloxacin 500 mg tablets	100	6,915	180	2.353	3.710	0.63
Clotrimazole cream 20gm	1	6,210	9	0.118	0.330	0.36
Cloxacillin 250 mg capsules	1000	400	1806	23.608	24.900	0.95
Cotrimoxazole 800 /160 mg, tablets	500	136,800	635	8.301	n/a	n/a
Cotrimoxazole 240 mg/5 ml suspension, 100 ml	1	500,000	21	0.268	n/a	n/a
Dapsone 100 mg, tablets	1000	4,500	880	11.503	9.700	1.19
Dispensing envelopes	1000	1,000	593	7.752	n/a	n/a
Doxycycline 100 mg capsules	100	1,750	120	1.569	1.170	1.34
Erythromycin tablets 500 mg	100	3,750	474	6.196	5.320	1.16
Fluconazole 200 mg tablets	100	170,000	575	7.516	14.550	0.52
Folic acid 5 mg tablets	1000	150	75	0.980	2.300	0.43
Griseofulvin 125 mg tablets	100	160	190	2.484	1.540	1.61
Griseofulvin 500 mg tablets	100	1,000	530	6.928	4.710	1.47
Hydrocortisone 1% cream	1	3,000	24	0.314	0.408	0.77
Hyoscine butyl bromide injection, 20 mg/ml ampoule	1	1,875	71	0.924	2.636	0.35
Ibuprofen 200 mg tablets	1000	30	340	4.444	5.100	0.87
Ibuprofen 400 mg tablets	500	4,360	235	3.072	4.350	0.71
Ibuprofen 100 mg/5 ml Syrup, 100 ml	1	4,450	22	0.286	0.410	0.70
Ketoconazole 200 mg tablets	30	4,994	54	0.706	1.794	0.39
Loperamide 2mg capsules	1000	1,220	650	8.497	7.000	1.21
Mebendazole 100 mg/ml suspension 30 ml	1	3,862	24	0.314	0.273	1.15
Metronidazole 200 mg tablets	1000	460	360	4.706	5.200	0.90
Metronidazole 200 mg/5 ml suspension, 100 ml	1	1,848	23	0.305	0.360	0.85
Metronidazole 400 mg tablets	1000	154	770	10.065	7.600	1.32
Multivitamin tablets	1000	180,000	330	4.314	n/a	n/a

Item	Pack Size	Quantity	KP Median Unit Price (KES)	KP Median Unit Price (USD)	Median International Price (USD)	Ratio
Multivitamin syrup, 100 ml	1	375,000	19	0.248	n/a	n/a
Nystatin 100,000 IU oral drops, 30 ml	1	141,750	26	0.340	0.852	0.40
ORS sachets (WHO formula) - 500 ml	100	946	330	4.314	5.960	0.72
Paracetamol 500 mg tab	1000	2,388	275	3.595	3.800	0.95
Paracetamol suspension 120 mg/5 ml, 100 ml	1	9,532	20	0.261	0.420	0.62
Prednisolone 5 mg tablets	1000	300	600	7.843	6.700	1.17
Pyridoxine 50 mg tablets	100	54,750	70	0.915	n/a	n/a

The average ratio of the Kenya Pharma median unit price to the international median unit price was 0.81:1.00, showing that the project was able to obtain significant savings.

### Registrations

Annex D contains tables regarding new certifications and registrations for the first project year. The first is a summary table. Subsequent tables show manufacturers from which Kenya Pharma procured commodities over the year. These tables list all the items the manufacturers produced and updated information on their certification and registration statuses with USFDA and the Kenya Pharmacy and Poisons Board. Additionally, as per contract requirements, the project obtained updated information on manufacturers' registration for different commodities in South Africa. This has been included because South African registration is often an indicator of upcoming USFDA certifications.

## ANNEX D. SUMMARY OF ARV REGISTRATION STATUS

Item International Non-Proprietary Name	Strength	Formulation	Unit Pack	USFDA Approval/Tentative Approval Status			Kenya Pharmacy and Poisons Board Registration			South Africa Registration (Please indicate Yes or No)
				Submitted for USFDA Approval/Tentative Approval (Yes or No)	Date of USFDA Approval/Tentative Approval Status (Indicate date of submission for products that are pending approval)	USFDA Approval/Tentative Approval Registration No.	Submitted for registration to the Pharmacy and Poisons Board of Kenya	Date of Pharmacy and Poisons Board Registration (Please indicate date of submission for products that are pending registration)	Registration Number	
Abacavir Sulfate	300 mg	Tablets	60s count	Tentative	17-May-06	ANDA 77-844	Approved	7-Apr-09	H2008/17685/460	Yes
Abacavir Sulfate	60 mg	Tablets	60s count	Tentative	12-Sep-08	NDA 22-293	Not submitted			
Abacavir Sulfate	20 mg/ml	Oral solution	240 ml	Tentative	27-Jun-06	ANDA 77-950	Approved	7-Apr-09	H2008/19998/504	Yes
Abacavir Sulfate and Lamivudine	60+30 mg 600+300 mg	Tablets	60s & 30s count 30s count	Tentative	19-Dec-2008 3-Sep-2008	NDA 22-295 NDA 90-159	Not submitted			
Didanosine	100, 150 & 200 mg	Chewable, dispersible, buffered tablets	60s count	Tentative	10-Jul-06	ANDA 77-275	Under review	31-Dec-2006		Yes
Didanosine	125, 200, 250 & 400 mg	Delayed-release capsules	30s count	Approved	24-Sep-08	ANDA 90-094	Under review (250 & 400 mg only submitted)	20-Sep-2008		Except 125 mg remaining strength are approved

Item International Non-Proprietary Name	Strength	Formulation	Unit Pack	USFDA Approval/Tentative Approval Status			Kenya Pharmacy and Poisons Board Registration			South Africa Registration (Please indicate Yes or No)
				Submitted for USFDA Approval/Tentative Approval (Yes or No)	Date of USFDA Approval/Tentative Approval Status (Indicate date of submission for products that are pending approval)	USFDA Approval/Tentative Approval Registration No.	Submitted for registration to the Pharmacy and Poisons Board of Kenya	Date of Pharmacy and Poisons Board Registration (Please indicate date of submission for products that are pending registration)	Registration Number	
Didanosine	10 mg/ml	Powder for oral solution	2 g: 100 ml 4 g: 200 ml	Approved	8-Mar-07	ANDA 78-112	Not submitted			Yes
Efavirenz	50, 100 & 200 mg	Capsules	50 & 100 mg: 30s count 200 mg: 90s count	Tentative	19-Dec-06	ANDA 78-064	Under review	11-July-2006		Yes
Efavirenz	600 mg 100 mg	Tablets	30s count	Tentative	24-Jun-05	ANDA 77-673 NDA 22-297	Under review (submitted only 600 mg)	3-April-2010		600 mg is approved
Efavirenz Tablets + Lamivudine and Zidovudine Tablets (Co-Package)	600 mg + 150-300 mg	Tablets (co-package)	6 x (5 x 3s Co-package)	Tentative	7-Mar-06	NDA 21-943	Under review	06-July-2006		
Emtricitabine	200 mg	Capsules	30s count	Tentative	9-May-08	ANDA 79-188	Under review	17-Oct-2008		
Emtricitabine and	200 mg + 300 mg	Tablets	30s count	Tentative	30-Mar-09	ANDA 90-513	Under review	28-April-2010		

Item International Non-Proprietary Name	Strength	Formulation	Unit Pack	USFDA Approval/Tentative Approval Status			Kenya Pharmacy and Poisons Board Registration			South Africa Registration (Please indicate Yes or No)
				Submitted for USFDA Approval/Tentative Approval (Yes or No)	Date of USFDA Approval/Tentative Approval Status (Indicate date of submission for products that are pending approval)	USFDA Approval/Tentative Approval Registration No.	Submitted for registration to the Pharmacy and Poisons Board of Kenya	Date of Pharmacy and Poisons Board Registration (Please indicate date of submission for products that are pending registration)	Registration Number	
Tenofovir Didsoproxil Fumarate										
Lamivudine	150 mg 300 mg	Tablets	60s count	Tentative	15-Jun-05	ANDA 77-464	Approved	06-Mar-2006	H2006/015 H2006/016	only 150 mg approved
Lamivudine	10 mg/ml	Oral solution	240 ml	Tentative	4-Nov-05	ANDA 77-695	Under review	13-May-2010		Yes
Lamivudine and Nevirapine and Stavudine	150,200,30 mg	Tablets	60s count	Withdrawn			Under review	22-Jan-2008		
Lamivudine and Nevirapine and Zidovudine	150,200,300 mg	Tablets	60s count	Tentative	30-Jun-06	NDA 21-939	Approved	7-April-2009	H2008/18121/475	
Lamivudine and Stavudine	150-30 mg 150-40 mg	Tablets	60s count	Not filed			Under review	07-Oct-2005		
Lamivudine and Zidovudine	150-300 mg 30-60 mg	Tablets	60s count	Tentative	7-July-2005 23-July-2009	ANDA 77-558 NDA 22-296	Approved (150-300 mg strength only filed)	06-Mar-2006	H2006/014	Yes

Item International Non-Proprietary Name	Strength	Formulation	Unit Pack	USFDA Approval/Tentative Approval Status			Kenya Pharmacy and Poisons Board Registration			South Africa Registration (Please indicate Yes or No)
				Submitted for USFDA Approval/Tentative Approval (Yes or No)	Date of USFDA Approval/Tentative Approval Status (Indicate date of submission for products that are pending approval)	USFDA Approval/Tentative Approval Registration No.	Submitted for registration to the Pharmacy and Poisons Board of Kenya	Date of Pharmacy and Poisons Board Registration (Please indicate date of submission for products that are pending registration)	Registration Number	
Lopinavir + Ritonavir	200-50 mg 100-25 mg	Tablets	200-50 mg: 120s count 100-25 mg: 60s count	Tentative	10-Mar-09	ANDA 90-471	Under review (200-50 mg only submitted)	29-May-2009		
Nevirapine	200 mg	Tablets	60s count	Tentative	20-Jun-05	ANDA 77-521	Approved	06-Mar-2006	H2006/017	Yes
Nevirapine	50 mg/5 ml	Oral suspension	240 ml	Tentative	29-Dec-05	ANDA 77-702	Under review	13-May-2010		Yes
Nevirapine	50 mg	Tablets for oral suspension	30s count	Tentative	24-Feb-10	NDA 22-299	Not submitted			
Stavudine	15, 20, 30 & 40 mg	Capsules	60s count	Approved	29-Dec-08	ANDA 77-672	Approved	15 & 20 mg: 07-April-2009  30 & 40 mg: 15-Nov-2005	15 mg: H2008/ 18516/682 20 mg: H2008/ 18517/683 30 mg: 17251 40 mg: 17252	Yes
Stavudine	1 mg/ml	Powder for oral solution	200 ml	Approved	29-Dec-08	ANDA 77-774	Under review	20-Feb-2006	-	Yes

Item International Non-Proprietary Name	Strength	Formulation	Unit Pack	USFDA Approval/Tentative Approval Status			Kenya Pharmacy and Poisons Board Registration			South Africa Registration (Please indicate Yes or No)
				Submitted for USFDA Approval/Tentative Approval (Yes or No)	Date of USFDA Approval/Tentative Approval Status (Indicate date of submission for products that are pending approval)	USFDA Approval/Tentative Approval Registration No.	Submitted for registration to the Pharmacy and Poisons Board of Kenya	Date of Pharmacy and Poisons Board Registration (Please indicate date of submission for products that are pending registration)	Registration Number	
Tenofovir Disoproxil Fumarate	300 mg	Tablets	30s count	Tentative	18-Feb-09	ANDA 90-647	Under review	04-May-2010		Yes
Zidovudine	300 mg 60 mg	Tablets	60s count	Approved	300 mg: 19-Sep-2005 60 mg: 23-Jul-2009	300 mg: ANDA 77-267 60 mg: NDA 22-294	Approved (300 mg only filed)	6-Mar-2006	H2006/018	300 mg is approved
Zidovudine	100 mg	Capsules	100s count	Approved	27-Mar-06	ANDA 78-128	Approved	2-Dec-2009	H2009/18596/682	
Zidovudine	50 mg/5 ml	Oral solution	240 ml	Approved	19-Sep-05	ANDA 77-268	Under review	13-May-2010		Yes

## **ANNEX E. ANNUAL QUALITY ASSURANCE REPORT SUMMARY, JULY 2010**

During its first year, Kenya Pharma focused on establishing systems and fine-tuning to apply potential efficiencies into its system. The project developed standard operating procedures for the QA department that considered integration of QA into supply chain steps; it applied these policies rigorously. The project adapted the procedures to the realities of implementation as it became more familiar with manufacturers and needs.

This is a summary of QA approaches and issues identified over the course of the year.

### **I. Year 1 QA Approach**

The Kenya Pharma QA system is robust to ensure safe HIV/AIDS pharmaceuticals for people living with HIV/AIDS in Kenya. The functional QA system improves the overall Kenya Pharma processes and is integrated into relevant stages in the supply chain, from product procurement to storage and delivery processes.

At the onset of the project, the QA manager, with an expatriate consultant, developed a document containing standard operating procedures for QA, including receipt of goods, waste disposal, product recall, procedures for handling product complaints, sampling, and inspection.

To ensure procurement of only high-quality products, Kenya Pharma accepts proposals for ARVs from only USFDA-approved/tentatively approved suppliers. Additionally, registration of the product with the Kenya Pharmacy and Poisons Board is mandatory. The QA manager participates on the proposal evaluation committee to provide this perspective and feedback.

For OI drugs, only manufacturers who are good manufacturing practices-compliant and Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme-certified were considered for award. This included a few local manufacturers who submitted proposals. Kenya Pharma QA is diligent to ensure that commodities are procured from manufacturers with stringent quality certifications/accreditations for highest quality standards.

During the majority of this first year, Kenya Pharma undertook sampling and inspection prior to shipping for 100 percent of the procured commodities. Following inspection was laboratory analysis for each batch of commodities. Vimta Labs was the primary source for analysis; it conducted the inspection and sampling at the India-based manufacturer's premises. In June 2010, the project adapted a policy by which 5 percent of the USFDA-approved/tentatively approved ARVs would be analyzed in the laboratories. During the course of the year, all batches of ARVs that were tested complied with the specifications for all the test parameters.

The QA manager conducted inspection and sampling of all OI drugs procured from local manufacturers. During these inspections, the QA manager inspected the manufacturers for

compliance with good manufacturing practices. Because of the reduced security found in the non-USFDA manufacturers, laboratory analysis was done for 100 percent of the batches. Due to the high numbers of batches, particularly of OI drugs, the project continued to use Vimta Labs but also sought out other WHO-prequalified laboratories to conduct the analysis, including the NQCL and MEDS.

Product sampling and inspection is undertaken at different points in the supply chain, including at the manufacturing site, at the time of loading for shipment, the time of receipt at our warehouse, and at SDPs. Samples are retained by the QA manager in the Kenya Pharma central warehouse.

## **II. QA standard failures**

### **a. Items transferred from MEDS**

At the start of the project, Kenya Pharma received inventory from MEDS for distribution. The shipper boxes transferred from MEDS were visually inspected for any labeling and packaging defects. Though most boxes complied, it was noted that a few had batch numbers that differed from the numbers on the packages inside. This was corrected immediately; the corresponding batch number was indicated on all boxes. It was also noted in a few instances that the number of packages indicated outside the shipper box did not match the number inside. This was also addressed immediately, including adjustment to the delivery note.

All stocks received from MEDS had accompanying QA reports that showed that commodities met the required standards for distribution. To provide additional insurance, an appropriate number of samples of the locally manufactured OI drugs were sent to NQCL for analysis. All received ARVs were from USFDA-approved manufacturers, so no samples were sent to the laboratory for analysis. Though most laboratory test results showed product compliance, one sample of Fluconazole 200 mg tablets failed to comply with the dissolution parameter. Upon verification from the MEDS quality file, it was noted that dissolution parameter was not tested for this product because it is not specified in the United States Pharmacopeia for Fluconazole tablets. This marginal non-compliance of the dissolution parameter did not warrant a recall. Furthermore, test reports were received after the products had been distributed and likely consumed.

### **b. Items Procured under Kenya Pharma**

Generally, Kenya Pharma has had positive results for products procured under this subcontract. After receipt by the warehouse staff, the QA manager visually inspects goods for defects against the signed delivery notes. The sampled shipper boxes and individual packages are also visually inspected for defects in shelf life, labeling, and packaging. During the fourth quarter, only one product did not comply with the packaging contract requirements: Nevirapine 200 mg tablets were not packaged in individual packs and, contrary to contract requirements, the patient leaflets were stuck on the bottles. Because the product was needed urgently and this issue did not compromise use of the product, the commodity was released

for distribution without hesitation. In addition, the manufacturer was informed to ensure that all future consignments complied with all the contract requirements and this partial non-fulfillment of the contract requirements would be used in past performance evaluation in future bids.

In May, Kenya Pharma initiated a product recall of Ciprofloxacin 500 mg tablets manufactured by Universal Corporation Limited after analytical reports from NQCL showed that the product failed to comply with the dissolution test parameter. Duplicate samples had been sent to NQCL and Vimta Labs. Vimta Labs released its analytical reports three weeks after it received the samples, showing that all tested batches complied. Based on these reports, the product was released for distribution. However, when NQCL released their analytical reports two months after it received samples, its results showed that all three batches failed to comply with the dissolution parameter.

On receipt of the NQCL reports, the QA manager instructed the warehouse not to distribute the Ciprofloxacin tablets, and SDPs were instructed not to dispense the drug further. Kenya Pharma decided to recall the distributed batches and the manufacturer was instructed to initiate investigation into the reasons for the non-compliance. Kenya Pharma then repeated the analysis for confirmation. Vimta Labs' re-analysis indicated that the product failed to comply with the dissolution parameter — results consistent with those from NQCL. Most of the quantities already distributed to the SDPs were returned to the warehouse and collected for replacement by the manufacturer. The manufacturer issued a comprehensive investigation report and replacement of the recalled product is due at the end of August 2010. The inconsistent test results were attributed to the hardening of tablets' coating over time. The Vimta results showed compliance because they were completed more quickly, before the hardening took place.

### **III. QA problems Identified by SDPs**

The Kenya Pharma QA manager has been vigilant throughout the year in monitoring concerns raised by SDPs regarding product QA. During the year, SDPs raised several concerns; all were addressed immediately and reported in the performance tables in quarterly reports:

- Two concerns were raised about products distributed by MEDS before the Kenya Pharma project began. These were forwarded to MEDS to be appropriately addressed.
- One concern raised on a few occasions regarded variations in drug presentation and packaging. This was due to the same commodity coming from different manufacturers. To address this, the Kenya Pharma field team worked with SDP staff to explain the U.S. government's procurement regulations, which cannot ensure that the same manufacturer can provide one product over long periods. SDPs were advised of different ways to help patients understand their regimens on a monthly basis.

- One report was of a potential adverse drug reaction to Cotrimoxazole tablets. Because this was an isolated incident, it was determined the reaction was an allergy or individual problem with the medication. The SDP was advised to switch the patient to Dapsone, which is also distributed by Kenya Pharma.
- Through the Kenya Pharma customer service and reporting mechanisms, some complaints were received by the project regarding products from other partners, such as Clinton Foundation. As these commodities (second line or pediatrics) were not our responsibility, these concerns were forwarded to the relevant parties.

## ANNEX F. QUARTER 3 ACCRUALS

Name of Partner: CHEMONICS INTERNATIONAL INC.  
 Name of Project: KENYA PHARMA  
 Agreement Number: 625-C-00-09-00014-00

Total Estimated Cost: 329,757,733  
 Obligated Funds: 80,327,000  
 Future Mortgage: 249,430,733

Project Start Date: July 6, 2009  
 Project End Date: July 5, 2012

Financial Status for the period ending: June 30, 2010  
 Date Prepared: May 28, 2010

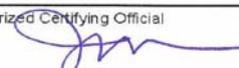
USAID Kenya Mission  
 Office of Health and Population  
 Financial Information: Accrual Estimates  
 Analyzed by Cognizant Technical Officer  
 or Activity Manager:  
 Name: .....  
 Signature: .....  
 Date: .....

	Funding Source						TOTAL	Cost Share
	PEPFAR	POP	MALARIA	TB	CHILD SURVIVAL	Avian Fluenza		
A. Obligated Funds to date:	80,327,000	-	-	-	-	-	80,327,000	-
B. Cumulative Expenditures (as of 3/1/3/2010):	6,819,500	-	-	-	-	-	6,819,500	-
C. Actual expenditures: 01-04-10 through 30-04-10	1,199,960	-	-	-	-	-	1,199,960	-
D. Accruals for current period (May & June 2010)	27,636,670	-	-	-	-	-	27,636,670	-
E. Total Accrued Expenditures (B+C+D) From Inception to date:	35,656,130	-	-	-	-	-	35,656,130	-
F. Remaining Balance (Pipeline): (A-E)	44,670,870	-	-	-	-	-	44,670,870	-
G. Estimated Expenditures for next quarter (ending 30/9/2010):	22,645,601	-	-	-	-	-	22,645,601	-
H. Projected Expenditure for next Quarter plus one October - December 2010:	22,025,269	-	-	-	-	-	22,025,269	-
I. Estimated remaining Length of Pipeline (LOP) monthly burn rate (After this Quarter in Row H):							-	

## FINANCIAL STATUS REPORT

(Short Form)

(Follow instructions on the back)

1. Federal Agency and Organizational Element to Which Report is Submitted  USAID	2. Federal Grant or Other Identifying Number Assigned By Federal Agency  PEPFAR	OMB Approval No. 0348-0038	Page of  pages
3. Recipient Organization (Name and complete address, including ZIP code) Chemonics International Inc. 1717 H Street NW Washington, DC 20006			
4. Employer Identification Number  52-2145827	5. Recipient Account Number or Identifying Number  623-C-00-09-00014-00	6. Final Report <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	7. Basis <input checked="" type="checkbox"/> Cash <input type="checkbox"/> Accrual
8. Funding/Grant Period (See instructions) From: (Month, Day, Year)  July 6, 2009	To: (Month, Day, Year)  July 5, 2012	9. Period Covered by this Report From: (Month, Day, Year)  April 1, 2010	To: (Month, Day, Year)  June 30, 2010
10. Transactions:			
	I Previously Reported	II This Period	III Cumulative
a. Total outlays	6,819,500	28,836,630	35,656,130
b. Recipient share of outlays	0	0	0
c. Federal share of outlays	6,819,500	28,836,630	35,656,130
d. Total unliquidated obligations			
e. Recipient share of unliquidated obligations			
f. Federal share of unliquidated obligations			
g. Total Federal share (Sum of lines c and f)			\$35,656,130.00
h. Total Federal funds authorized for this funding period			80,327,000.00
i. Unobligated balance of Federal funds (Line h minus line g)			44,670,870.00
11. Indirect Expense			
a. Type of Rate (Place "X" in appropriate box) <input checked="" type="checkbox"/> Provisional <input type="checkbox"/> Predetermined <input type="checkbox"/> Final <input type="checkbox"/> Fixed			
b. Rate	c. Base	d. Total Amount	e. Federal Share
12. Remarks: Attach any explanations deemed necessary or information required by Federal sponsoring agency in compliance with governing legislation.			
13. Certification: I certify to the best of my knowledge and belief that this report is correct and complete and that all outlays and unliquidated obligations are for the purposes set forth in the award documents.			
Typed or Printed Name and Title Jay Drosin Chief of Party		Telephone (Area code, number and extension)  (254) 20 3861991 Ext.122	
Signature of Authorized Certifying Official 		Date Report Submitted  4-June-2010	

NSN 7540-01-218-4387

269-202

Standard Form 269A (Rev. 7-97)  
Prescribed by OMB Circulars A-102 and A-111

**U.S. Agency for International Development**

1300 Pennsylvania Avenue, NW

Washington, DC 20523

Tel: (202) 712-0000

Fax: (202) 216-3524

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