

## **Assessing the Procurement, Distribution, and System-Strengthening Needs for the Pharmaceutical System in the Democratic Republic of the Congo, October 2008**

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## **About SPS**

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to and appropriate use of medicines.

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## ACRONYMS

AIDS	acquired immunodeficiency syndrome
AQ	amodiaquine
AS	artesunate
BCAF	Bureau de Coordination des Achats de la FEDECAME (Office for the Coordination of Purchases of FEDECAME)
BCC	behavior change communication
BCZS	Bureau Central de Zone de Santé (Health Zone Central Office)
BTC	Belgian Technical Cooperation
CDC	U.S. Centers for Disease Control and Prevention
CDR	Centrale de Distribution Régionale (Regional Distribution Center)
CRS	Catholic Relief Services
DPM	Directorate of Pharmacies, Medicines, and Traditional Medicine
DRC	Democratic Republic of the Congo
EDF	European Development Fund [European Union]
EDS	Enquête Démographique et de Santé
EU	European Union
FEDECAME	Fédération des Centrales d'Approvisionnements en Médicaments Essentiels (Federation of Essential Medicine Procurement Agencies)
FHI	Family Health International
FP	family planning
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
HIV	human immunodeficiency virus
HMIS	health management information system
HPI	Health Policy Initiatives
HZ	health zone
IDA	International Dispensary Association
MCH	Maternal and Child Health
MoH	Ministry of Health
MSH	Management Sciences for Health
NEML	National Essential Medicines List
NMCP	National Malaria Control Program
OFIDA	Office des Douanes et Accises (Customs and Excise Office)
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PMIS	pharmaceutical management information system
PMTCT	prevention of mother-to-child transmission
PNAM	Programme National d'Approvisionnement en Médicaments essentiels (National Essential Medicine Supply Program)
PNLS	Programme National de Lutte contre le Sida (National HIV/AIDS Program)
PNT	Programme National de Lutte contre la Tuberculose (National Tuberculosis Program)
PSI	Population Services International

SNAME	Système National d'Approvisionnement en Médicaments Essentiels (National System for Procurement of Essential Medicines)
SPS	Strengthening Pharmaceutical Systems Program
STG	standard treatment guideline
TB	tuberculosis
TOT	training of trainers
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
USD	U.S. dollar
VCT	voluntary counseling and testing
WHO	World Health Organization

## EXECUTIVE SUMMARY

In October 2008, the U.S. Agency for International Development (USAID) Mission in the Democratic Republic of the Congo (DRC), recognizing the key importance of a well-functioning pharmaceutical system for the well-being of the Congolese population as well as the magnitude of the challenges for improving health outcomes and the effectiveness of USAID's programs, undertook an assessment of the national pharmaceutical system. USAID in Washington and the USAID-funded Strengthening Pharmaceutical Systems (SPS) Program provided technical assistance.

The assessment's overall objectives were to evaluate the gaps and vulnerabilities of the pharmaceutical supply chains currently used by the Mission and, more broadly, to determine the type and extent of technical assistance required to strengthen the capacity of the Congolese pharmaceutical system to support the Ministry of Health's strategy for providing the Congolese population with a minimum essential package of quality health services.

The assessment team used the following methodology in performing its work—

1. Define the scope as clearly as possible.
2. Perform desk research by reviewing applicable laws and decrees; published national documents such as national policies, strategies, and implementation plans; and existing reports and studies by various donors, implementers, and government bodies.
3. Interview a wide range of stakeholders in Kinshasa as well as in and around Kisantu and Kananga.
4. Perform analyses and product quantifications.
5. Recommend a range of interventions at multiple levels of the system.
6. Write the current report.

In its investigation of the root causes behind the identified gaps in the pharmaceutical system, the team has studied the following key components of the system—

- Laws on the books, regulations and policies in place, and strategies in effect
- Administrative and institutional architecture of the health sector
- The pharmaceutical supply market, using a whole-market approach
- The operational links in the pharmaceutical supply chain, from funding mechanisms to reporting practices and from procurement to customer dispensation

## **Summary of Findings**

The following main strengths of the DRC pharmaceutical system were identified during the assessment—

- National pharmaceutical policy, strategic plan, and other key documents (NEML) have been developed.
- A large number of donors and implementing partners support the system.
- A vast network of robust nongovernmental and faith-based organizations runs the primary health care system.
- The workforce is well educated and resilient.
- The national essential medicines procurement system (Fédération des Centrales d'Approvisionnement en Médicaments Essentiels [Federation of Essential Medicine Procurement Agencies; FEDECAME] and the Centrales de Distribution Régionale [Regional Distribution Centers; CDRs]) exists and is supported financially by the 9th European Development Fund (EDF) of the European Union (EU).

The main weaknesses include the following—

- A perceived lack of political and operational leadership by the Ministry of Health (MoH)
- The very small government budget allocated to and executed for the public's health
- The lack of enforcement of the regulations governing the distribution of medicines in the private sector, resulting in unfair competition and an incentive for public sector actors to pursue monetary gains detrimental to the customers
- The lack of capacity and accountability of several key players, such as the Directorate of Pharmacies, Medicines, and Traditional Medicine (DPM), the national laboratories, and the provincial and district counterparts of the DPM
- A disorganized and wasteful system stemming from the multiplicity of parallel and largely unaccountable pharmaceutical supply chains that creates gainful opportunities for individuals and a built-in disincentive for transparent reform
- The absence of a dynamic and competitive transportation market
- The lack of a well-functioning rail transportation network
- An unaware and disempowered clientele

## Key Recommendations

In view of the identified challenges, the team recommends the following short-term actions by the Mission—

- Create a full time Activity Manager position responsible for overseeing all USAID-supported procurement of pharmaceuticals and health supplies, deliveries, and system-strengthening technical assistance efforts, including cooperation with the U.S. Centers for Disease Control and Prevention (CDC), the government of the DRC, donors, and other partners.
- Strategically target a number of health zones and select a few high-impact pharmaceuticals for procurement and delivery in function of (a) current program priorities, (b) absence of or insufficient service provision, and (c) local supply chain management capacity (CDRs, districts, and health zones).
- Within the framework of the Inter-donor Group (known as the GIB), propose the creation of a Pharmaceutical System Committee under the chairmanship of the Minister of Health or his empowered delegate with a view to coordinate all efforts relating to the strengthening of the *Système National d'Approvisionnement en Médicaments Essentiels* (National System for Procurement of Essential Medicines; SNAME).

Over the long term, and leveraging the expertise of one or more contracting agencies, the team recommends the following USAID interventions (among others)—

- Join the FEDECAME as an active member, that is, as both a provider and a recipient of services.
- Advocate with the DRC government
  - For the need to prosecute hazardous private sector practices by
    - Enforcing existing regulations
    - Issuing relevant new regulations (provided a commitment and the capacity to enforce them)
  - For the need to fully exempt from taxes all pharmaceutical and health commodities imports
- Advocate with the MoH for the dissolution of the DPM and its reemergence as an *Agence du Médicament* (Medicine Agency) with new statutes and bylaws guaranteeing its financial independence, its enforcement authority, and a strictly merit-based recruitment process.

- Strengthen the contracting and commercial capacities of the FEDECAME by providing full-time commercial procurement technical assistance over an extended period while ensuring the standards for the FEDECAME to become a recipient of U.S. government funds are progressively and sustainably met.
- Strengthen the oversight capacity of the Provincial Inspecting Pharmacist (MIP) and the District Inspecting Pharmacist (DIP).

# INTRODUCTION

## Background

With an area comparable to that of Western Europe, the Democratic Republic of the Congo, formerly Zaire, is Africa's third-largest country after Algeria and Sudan. Surrounded by nine countries, the DRC has only limited coastline on the Congo River's estuary at the Atlantic Ocean in Boma. Although the country's soil contains immense mineral resources, the DRC is one of the world's poorest countries. A civil war that resulted in the ousting of dictator Mobutu Sese Seko and an international war involving countries as far away as Namibia and Zimbabwe are directly or indirectly responsible for the death of about 4 million Congolese, a further breakdown in infrastructure after decades of neglect, and crushing blows to the economy. The first universal elections ever, in August 2006, installed Joseph Kabila as the current president and paved the way for a new constitution in an attempt at strengthening the country's fragile stability.

The DRC's health system is struggling with high levels of mortality and morbidity. A lack of access to good-quality health care compounds the impact of high birth rates, malnutrition, malaria, tuberculosis (TB), and other conditions. According to the 2007 Demographic and Health Survey, the contraceptive prevalence rate for modern methods is only 6 percent (women in union), 46 percent of children under five years of age suffer from chronic malnutrition, and HIV prevalence is 1.3 percent. In 2004, the prevalence of TB per 100,000 population was estimated at 551. Life expectancy at birth is 43 years. The national health strategy calls for access by all Congolese to an integrated basic health care package provided at the health-center level. The territory is divided into more than 500 health zones (HZs), each covering an approximate population of 100,000. Health zones feed into districts, which feed into provinces. The new constitution creates 26 provinces with enhanced autonomy. The Ministry of Health in Kinshasa is responsible for setting policy and making regulations, while the provincial ministries are responsible for implementing and supporting health services.

The withdrawal of government support in the 1990s left HZs and individual facilities with independent responsibility for health commodity procurement. In many cases, service providers continue to purchase medicines and health commodities from private sources that charge lower prices because of the absence of quality control. In an effort to tackle this problem, the central MoH has designed—but cannot fund—a central procurement and distribution system, the SNAME. In 2004, the DRC government signed an agreement with the Fédération des Centrales d'Approvisionnement des Médicaments Essentiels to allow its network of provincial medical stores to take over import, distribution, and provision of medicines and pharmaceutical commodities throughout the country. The EU and the Belgian Technical Cooperation (BTC) have backed this effort. Although donors and nongovernmental organizations have already set up their own systems, the MoH encourages all its supported HZs to rely on the FEDECAME supply system. The system does not currently procure condoms, antiretrovirals, or contraceptives, but it distributes these products through its CDRs.

## **Current USAID Health Program**

The current U.S. Agency for International Development health program supports the MoH's national strategy for providing universal access to a minimum package of good-quality health services. USAID's activities include service delivery; strengthening local capacity in management, supervision, and service provision; and improving medicine supply in 82 HZs in central and eastern Congo. Through its partners, USAID operates in four provinces: Kasai-Occidental and Kasai-Oriental, Katanga, and Sud-Kivu. At the central level, USAID has supported routine immunization, polio eradication, and measles reduction activities. To help with the enormous malaria problem, USAID has supported the development and implementation of a revised national malaria policy, including the introduction of insecticide-treated nets in several HZs. USAID has assisted the national TB program (Programme National de Lutte contre la Tuberculose; PNT) to expand the DOTS strategy, to establish a referral laboratory system ensuring quality control measures, and to strengthen national and provincial-level capacity in Sud-Kivu, Maniema, Kasai-Occidental, and Kasai-Oriental. Support has also begun for the national reproductive health program.

In the focus cities of Bukavu, Lubumbashi, and Matadi, the current USAID/DRC HIV/AIDS program supports—

- HIV/AIDS prevention for the general population as well as high-risk groups, behavior change communication (BCC), and peer education, including socially marketing condoms through Population Services International (PSI)
- Community-based palliative care for people living with HIV/AIDS through Catholic Relief Services (CRS), World Vision, and local partners
- Support for orphans and vulnerable children (education, nutrition, occupational training and income-generating activities) through CRS, World Vision, and local partners
- Voluntary counseling and testing (VCT) in a mix of clinical and community settings, with Family Health International (FHI), the MoH, and others
- Referrals to the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), the World Bank Multi-Country HIV/AIDS Program, and other donor programs

In rural health zones, USAID also supports HIV programs through—

- Prevention of mother to child transmission (Project AXxes), primary health care, and blood safety (Safe Blood for Africa)
- Public-private partnerships: cooperation with MIDEMA in Bas-Congo and mining companies in Katanga to provide treatment for HIV/AIDS and sexually transmitted infections treatment, encourage blood safety, prevent mother to child transmission, and support prevention

At the national level, USAID also supports HIV/AIDS efforts through—

- Coordinating with the National HIV/AIDS Program (Programme National de Lutte contre le Sida; PNLs), the National Multi-sector HIV/AIDS Program, and other donors for targeting programs according to identified needs as part of the Partners’ Forum
- Building capacity within the Ministry of Social Affairs to implement the Orphans and Vulnerable Children National Plan of Action (Constella Futures)
- Serving as second vice-president on the GFATM Country Coordination Mechanism
- Providing substantial funding and rallying donors to complete the DRC’s first-ever Demographic and Health Survey

Table 1 provides an overview of current USAID-supported activity.

**Table 1. USAID Current Activity Summary**

<b>Program Elements</b>	<b>Project</b>	<b>Activities</b>	<b>Geographic Location</b>
Maternal and Child Health (MCH)	Project AXxes	Service delivery	Sud-Kivu, Katanga, Kasai-Occidental and Oriental
	CRS	Service delivery	Kasai-Occidental and Oriental
	UNICEF	Polio	Nationally
Infectious Diseases	TB Control Assistance Program (USAID)	TB technical assistance	National level and Maniema, Kasai-Occidental and Oriental, Sud-Kivu
	Project AXxes	Service delivery	Sud-Kivu, Katanga, Kasai-Occidental and Oriental
	World Health Organization	Surveillance	National level
	Management Sciences for Health/Strengthening Pharmaceutical Systems Program (MSH/SPS)	Malaria	Sud-Kivu, Katanga, Kasai-Occidental and Oriental
	UNICEF	Malaria	Sud-Kivu

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<b>Program Elements</b>	<b>Project</b>	<b>Activities</b>	<b>Geographic Location</b>
Reproductive Health/Family Planning (FP)	Project AXxes	Service delivery	Sud-Kivu, Katanga, Kasai-Occidental and Oriental
	FP and Condom Social Marketing	Social marketing of condoms, FP methods, Pur water filters	Kinshasa, Lubumbashi, Bukavu, Uvira
	Awareness Project (Georgetown)	Standard days FP method	Nationally
	ACQUIRE (Jane Goodall Institute)	Population and environmental conservation	Nord-Kivu
	FP/HIV integration (FHI)		Kinshasa
	Central Contraceptive Procurement (USAID)	Contraceptive procurement	DRC-West
HIV/AIDS	CRS	Care and support	Bukavu, Matadi, and Lubumbashi
	FHI	VCT	Bukavu, Matadi, and Lubumbashi
	PSI	BCC	Bukavu, Matadi, and Lubumbashi
	ROADS (FHI)	BCC, VCT, care and support, and capacity building	Bukavu
	FHI (Global Development Alliance with Seaboard)	Prevention care and support and treatment program	Matadi
	Project AXxes	Blood safety	Sud-Kivu, Katanga, Kasai-Occidental and Oriental
	Safe Blood for Africa (Global Development Alliance)	Blood safety	Sud-Kivu, Katanga, Kasai-Occidental and Oriental and national level
	Health Policy Initiatives (HPI) Task Order 1	Orphans and other vulnerable children (OVC) Rapid Country Assessment, Analysis, and Action Planning (RAAAP) OVC RAAAP	National level
	HPI Task Order 1	Support to the Ministry of Social Affairs	National level

USAID and other donors procure and provide medicines and other commodities to the programs they directly support. For example, the United Nations Children’s Fund (UNICEF) provides malaria supplies, the Global AIDS Vaccine Initiative supplies vaccines, and the United Nations Population Fund (UNFPA) provides contraceptives. In addition, each donor (USAID, World Bank, GFATM, and so on) supplies the HZs in which it works.

This fragmented “system” presents a number of challenges, including the following—

- Lack of sustained access to commodities such as medications over the long term, specifically when programs end
- Loss of cost savings and opportunity for purchasing medications and other commodities using economies of scale
- Variable drug quality assurance and supply chain effectiveness according to each purchaser’s level of oversight

### **Scope of Work**

USAID/DRC requests an assessment team to collect additional information that will allow the Mission to make appropriate decisions on programming new activities in the areas of commodity procurement and health-system strengthening. The assessment team will focus on providing information that addresses the following questions and issues—

1. With a focus on the USAID- and the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR)-supported activities and in the short term—
  - What are the estimated next-year requirements of selected health commodities and medical supplies for the USAID- and PEPFAR-supported programs that support the DRC MoH’s minimum package of health activities, with a focus on malaria, MCH, HIV/AIDS, and reproductive health? (*Note:* The list of selected products for quantification was developed following discussions with USAID/DRC at the beginning of the assessment.)
  - Do any issues exist with the DRC drug regulatory authority regarding the particular products the U.S. government plans to bring into the country through its centrally funded mechanisms (e.g., Central Contraceptive Procurement), such as registration, importation, distribution to appropriate levels of care, or pharmacovigilance?
  - What are the gaps in the supply chain management capacity in USAID- and PEPFAR-funded facilities, and what improvements are needed?
  - What is the assessment team’s analysis of the respective merits and drawbacks of a scenario for ensuring a well-performing commodity distribution system in support of USAID/DRC’s health program?

- What does the assessment team recommend to set up a USAID commodity system (offices, settlements in the country, warehousing, point of entry, transportation means, and so on)?
2. In a national context and with a long-term perspective—
- How would a USAID program strategically contribute to improvements that would give other donors confidence in using the government commodity supply system?
  - What political, human, financial, or other resource challenges are hindering the development of stronger pharmaceutical management capacity in the country? What are some ways to overcome those challenges?
  - What are the main issues when dealing with the commodity procurement cycle in the DRC at different levels?
  - What is the status of the FEDECAME network in terms of policies, regulations, and guidelines for the appropriate management and use of medicines and health commodities, and what is still needed to improve the system?
  - What else should be done to advance the country's capacity in procurement and distribution of commodities?

## **Methodology**

In accordance with the budget available, the evaluation team will collect and analyze data using a collaborative and participatory approach.

Evaluation tools (questionnaire, discussion guides, and the like) will be developed, and other methods will be used as appropriate (documentary review, observation, and so on) to focus on the evaluation questions listed in the Scope of Work. The Mission will provide the assessment team with the necessary briefing materials to conduct the assessment properly.

The Mission will work with the assessment team to develop a list of stakeholders for key informant interviews. The assessment team will seek qualitative and quantitative information using all necessary interview methods (face to face, telephone call interviews when necessary).

At the end of the assessment, the team will hold a debriefing meeting with the USAID health team to present preliminary findings and recommendations. A debriefing meeting will also be held with the USAID Mission director to present the results and outcomes of discussions with stakeholders. In collaboration with the USAID health team, the assessment team will review the findings and confirm that data are correct and conclusions are sound. They will discuss recommendations and identify priority interventions and next steps based on these discussions.

## **Caveats and Limitations**

- In addition to collecting information relevant to the scope of work, each team member focused his or her questions on particular aspects, depending on his or her individual areas of expertise and set of skills. To ensure a comprehensive understanding and a more thorough and interdisciplinary analysis of the pharmaceutical system, the whole team conducted the key informant interviews together.
- Because of time limitations, the team was able to visit only two provinces besides Kinshasa: Bas-Congo and Kasai-Occidental. In Bas-Congo, the team visited the CDR in Kisantu, interviewed one district medical chief (*médecin chef de district*), and visited the Bureau Central de Zone de Santé (BCZS; Health zone central office) of Sona Bata. In Kasai-Occidental, the team visited the Kananga CDR, one BCZS, and one health center.
- Time limitations prevented the team from visiting one or more labs.
- Time limitations did not allow the team to divert from its focus on the public sector pharmaceutical supply chain and explore the strengths and weaknesses of the private pharmaceutical sector, although the team interviewed two major commercial freight companies involved with the transportation of pharmaceuticals and health supplies in DRC.
- Because consumption-based statistics are virtually unavailable in DRC, all quantity requirements for the team's selected commodities have been based on demographic data and information provided by some key informants.
- Although the team visited a number of public and private sector warehouses, it did not perform a survey using standardized assessment tools. Similarly, although the team focused on the governance component of the FEDECAME, it did not perform a systematic audit of its internal procedures.



## OVERVIEW OF THE HEALTH SYSTEM

The public sector health care system in the DRC has three levels: central, intermediate, and peripheral.

In addition to the office of the Minister and the General Secretary of the MoH, the central level includes the various directorates and the disease-specific programs. The intermediate level is represented by the Provincial Inspectorates. In addition, provincial ministries of health are about to emerge in accordance with the move toward greater local autonomy granted by the new constitution. While the central level will retain overall responsibility for national policy setting and regulation making, the intermediate level will be increasingly responsible for translating policy into implementation, and coordinating and supervising the activities of the peripheral level.

The key unit of the peripheral level is the health zone, an administrative area that typically covers a population of about 100,000 people. Each HZ is organized around a BCZS, which includes a general referral hospital and is divided into health areas where health centers operate. HZs are responsible for providing each Congolese access to an essential minimum package of health services, in accordance with the national health strategy. There are currently more than 6,000 health centers scattered across 515 HZs covering the country.

As far as health commodity security is concerned, the MoH has recently introduced a new national pharmaceutical policy instituting the National Essential Medicine Supply Program (Programme National d'Approvisionnement en Médicaments essentiels; PNAM). The strategy calls for pooling pharmaceutical procurement through FEDECAME to leverage economies of scale, combined with a decentralized distribution system supported by a network of existing faith-based or nongovernmental-organization-run distribution hubs that will become full-fledged CDRs in charge of purchasing and forwarding the appropriate selection and quantity of pharmaceuticals to the peripheral levels and ultimately to the health centers. In addition, the sustainability of SNAME rests on a cost-recovery mechanism launched and supported by the EU's 9th EDF through its opening of credit lines.



## SUMMARY OF THE ASSESSMENT FINDINGS

### Organization of the DRC Pharmaceutical Sector

The pharmaceutical sector in DRC is highly fragmented, with little or no governmental oversight. There are multiple parallel pharmaceutical supply systems for public sector health facilities. The supply system for any particular public health facility depends largely on the donor supporting the HZ within which the health facility is located. In the event the donor supporting the HZ changes, then the pharmaceutical supply system for health facilities in that HZ would likely also change.

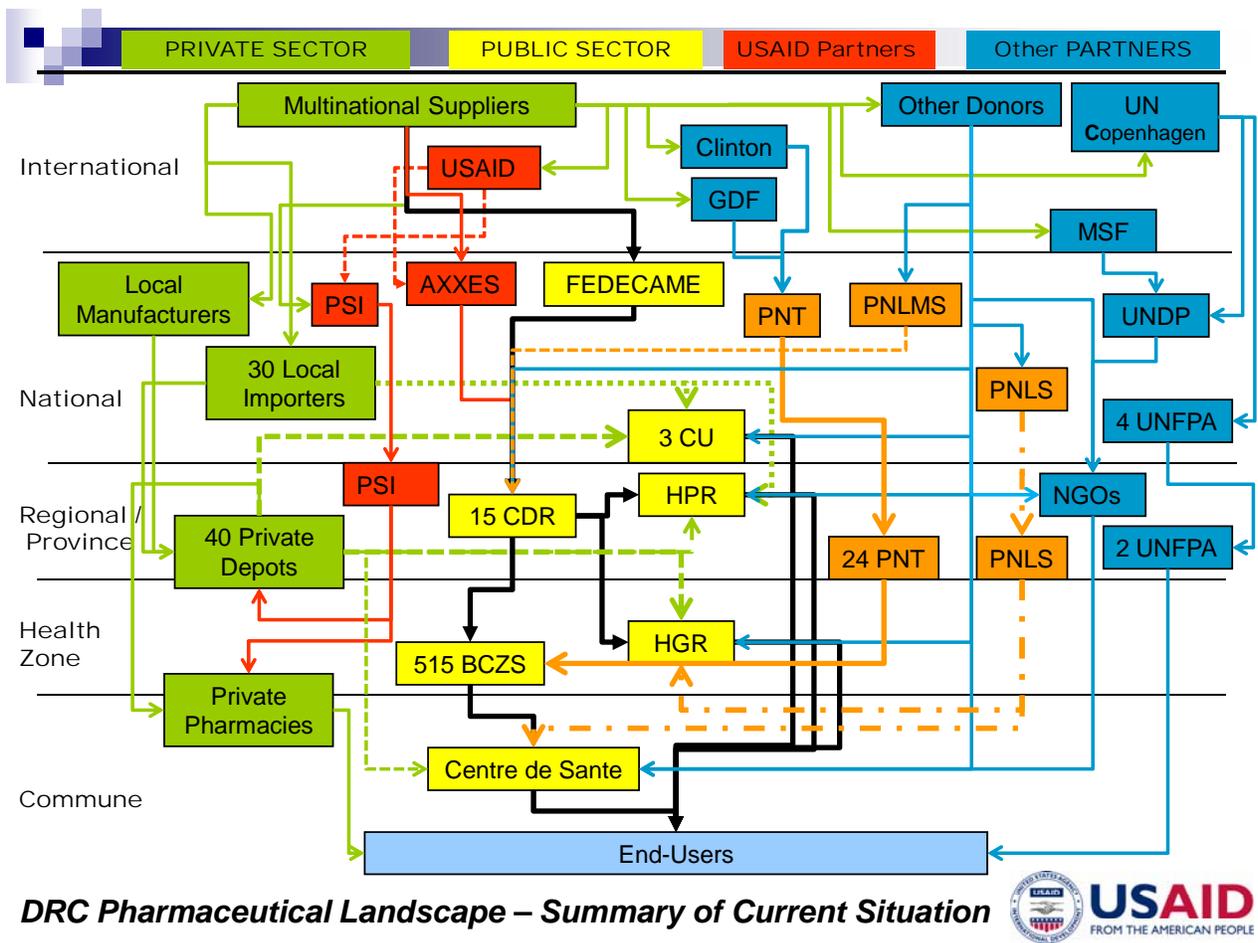
Based on the interviews conducted and the documents reviewed during this assessment, the team summarized the flow of pharmaceutical products in the various pharmaceutical supply systems that were in use by those interviewed as shown in Figure 1, which demonstrates the highly fragmented pharmaceutical landscape in DRC.

### *Directorate of Pharmacies, Medicines, and Traditional Medicine*

Created within the MoH by Order 82-027 of March 19, 1982, the DPM is the division charged with responsibility for overseeing the pharmaceutical sector in DRC. The DPM has six main divisions—

- Pharmaceutical Management
- Pharmaceutical Laws and Regulations
- Quality Assurance
- Narcotics Control
- Promotion of Traditional Medicines
- Cosmetics and Para-pharmaceutical Products

These six divisions are further divided into 16 offices and 20 cells. Each of the 11 provinces has a pharmacist or a pharmacy technician, and the DPM plans to assign a pharmacy technician to each district as well. As part of the decentralization process, the DPM national office will be responsible for developing policies and regulations while the provincial offices will be responsible for implementing them.



Note: CU = Centres Universitaire (University Hospital); GDF = Global Drug Facility; HGR = Hôpital General de Référence; HPR = Hôpital Provinciale de Référence; MSF = Médecins Sans Frontières; NGO = nongovernmental organization; PNLMS = National Multisectoral Program against AIDS; UNDP = United Nations Development Programme.

**Figure 1. Pharmaceutical supply cycle in the DRC**

The DPM is currently the weakest link within the public pharmaceutical supply system. It is not fulfilling its oversight and regulatory role over the pharmaceutical sector, which has created a vacuum that has contributed to the fragmented pharmaceutical landscape illustrated in Figure 1. The DPM as it is currently structured faces several challenges, including the following—

- Limited “voice” or status within the MoH: The MoH as currently structured has 13 directorates and several programs. A directorate or program without dynamic leadership and without external donor support does not have sufficient traction within the MoH leadership.
- Limited financial support: The DPM is wholly financed by the government budget and from funds generated from the registration of pharmaceuticals products. As discussed in

subsequent sections of this report, this financial support is currently inadequate to meet the true operational needs of the DPM.

- **Limited human resources capacity:** On paper, the DPM requires 203 staff members, including 36 pharmacists. At the time of the assessment, however, it had 67 staff members, including 28 pharmacists, and 7 pharmacy technicians. The technical staff has had no recent training in pharmaceutical management, and the management staff is not sufficiently trained in leadership and management skills. Most were selected because of their long period of service within the public sector.
- **Insufficient equipment and tools:** The operations of the DPM are currently primarily paper based. The World Health Organization (WHO) donated computers for use in the central office of the DPM in August 2008. Previously, the only computer available was used by the secretarial pool. The new computers were not yet operational because the staff needed to complete training in basic computer skills. This training had begun at the time of the assessment although the staff was not clear on when they expected to start using the computers.
- **Poor remuneration of staff.**

In 2007, WHO completed an evaluation of the pharmaceutical sector in DRC that recommended an overhaul of the DPM with the creation of an independent medical agency that would be able to generate and retain its own revenue and be independent from political influence over its operations. Such a system would help alleviate some of the challenges that are currently hampering the operations of the DPM.

### ***National System for Procurement of Essential Medicines***

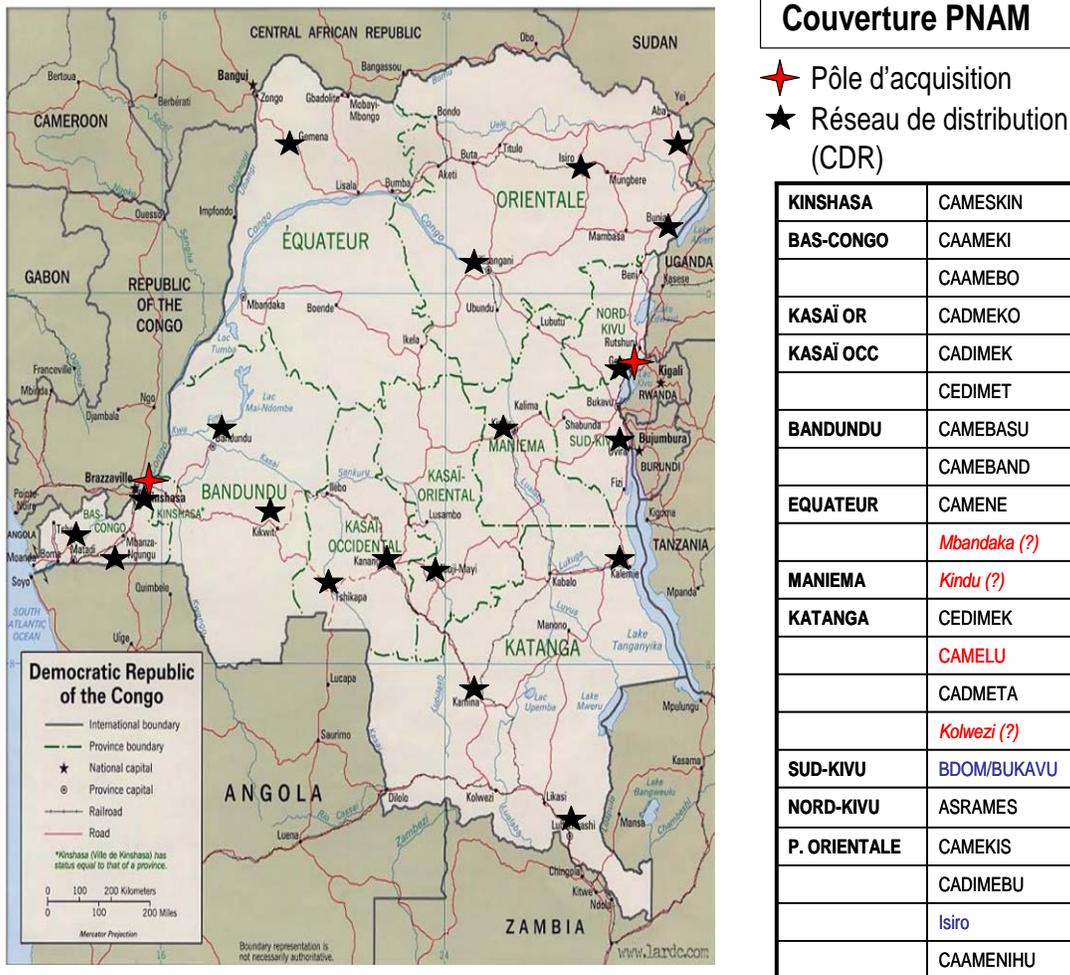
In 2002, following a feasibility study, the MoH established the National System for Procurement of Essential Medicines with the following key objectives<sup>1</sup>—

- To centralize procurement of essential medicines through a nonprofit central purchasing agency. FEDECAME, which evolved from a preexisting pooled procurement facility used by the protestant church in DRC, was contracted to serve as this central purchasing agency.
- To decentralize the distribution of medicines in the peripheral areas through the development of a network of 30–40 regional distribution depots (CDRs). The current distribution of CDRs is shown in Figure 2: 17 CDRs (listed in black and blue in the legend of Figure 2) and three other regional depots planned for upgrading to CDR level (listed in red in the legend in Figure 2). Two provinces, Sud-Kivu and Maniema, do not currently have a CDR, although a potential CDR has been identified for Sud-Kivu.

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<sup>1</sup> République Démocratique du Congo. Ministre de la Santé. Juillet 2006. Plan Directeur Pharmaceutique National.

FEDECAME and the CDRs are essentially nonprofit private sector organizations that the MoH has contracted to supply the public sector pharmaceutical supply system. The contract between FEDECAME and the MoH was renewed in 2008 for another five years. To coordinate, supervise, and evaluate the implementation of SNAME, the MoH has established a program within the DPM, the PNAM.



Source: PNAM.

Figure 2. Distribution of CDRs in the DRC, 2008

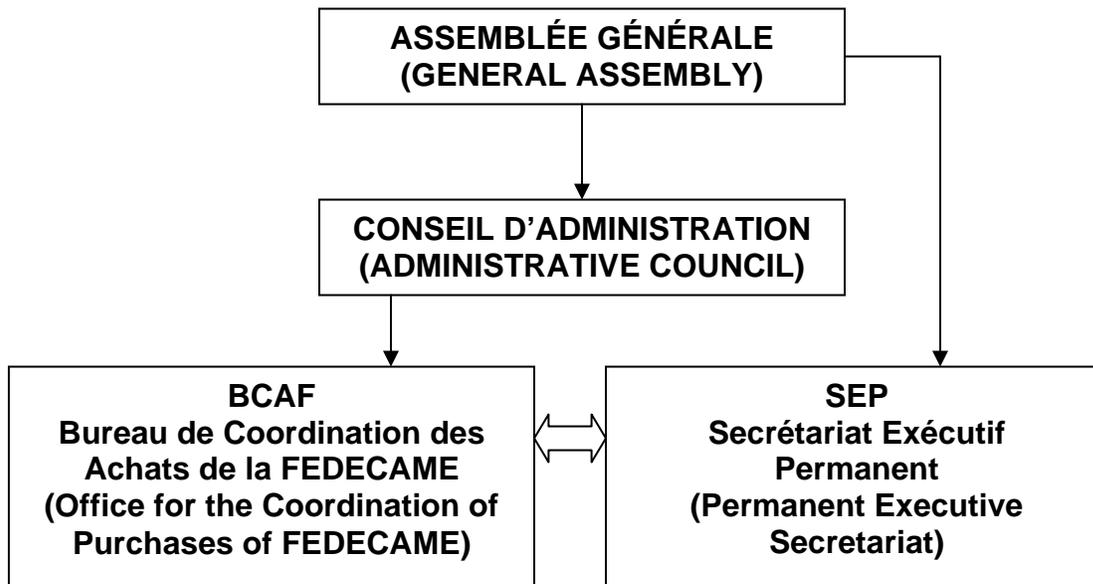
## FEDECAME

FEDECAME has three primary responsibilities—

- Conduct procurements for the public sector pharmaceutical supply system
- Ensure quality of the products procured for the public health sector pharmaceutical supply system

- Provide technical and logistical support for the CDRs within SNAME

A general assembly of members that consists of representatives of the affiliated CDR, representatives of the government (MoH, Ministry of Finance), and representatives of the health sector partners oversees the activities of FEDECAME. The administrative structure of FEDECAME is summarized in Figure 3.



Source: FEDECAME.

**Figure 3. Administrative structure of FEDECAME**

The Office for the Coordination of Purchases of FEDECAME (BCAF) is responsible for conducting its procurements. The Permanent Executive Secretariat is responsible for evaluating the service provided to the CDR by the BCAF and ensuring an effective interface between FEDECAME and other institutions.

FEDECAME is currently facing several challenges that affect its ability to fully meet its mandate—

- Nonfulfillment by the government of its requirements under the contract signed with FEDECAME—
  - The DRC government does not conduct all its procurements of pharmaceutical supplies through FEDECAME as is expected.
  - The government has not removed all the taxes and fees on pharmaceutical products procured through FEDECAME.

- Reliance on donors for funds to meet operational costs: Although FEDECAME has generated increasing revenues each year since its inception, it is still very reliant on donor support or immediate payment for orders to meet its current operating needs. It has no separate capital reserves. FEDECAME has determined that it requires 1.5 million U.S. dollars (USD) to meet its current operating costs. Of this, USD 1 million is required to facilitate prepayment of suppliers (in case of delayed payment by the CDR), and USD 0.5 million is required to purchase safety stock.
- Differing requirements by different donors.
- Insufficient capacity to provide the technical support to CDR and quality assurance as outlined in its mandate

### **CDRs**

The CDRs are all nonprofit private depots that have been contracted by the MoH to serve as regional warehouses for the public sector pharmaceutical supply system. A private depot must submit to an evaluation by PNAM to be upgraded to a CDR. PNAM has developed specific standards guiding the operations of a CDR. Most of the CDRs currently included within SNAME have evolved from depots previously managed by the faith-based community.

PNAM has estimated that the average CDR needs to generate revenues of at least USD 15,000 to meet its operating costs. None of the CDRs is currently generating sufficient revenues; therefore, they are still dependent on outside financial support. As a result, although 21 CDRs are currently listed within SNAME, as seen in Figure 2, only 9 are functioning well. Of these 9, CAMESKIN in Kinshasa and CAMEKI in Kisantu do not have a lot of donor support but are generating sufficient revenue to support their activities. Three—CAMEBASU in Kikwit, CAMEBO in Matadi, and CAMENI in Buamanda—are subsidized by the BTC; ASRAMES in Goma is subsidized by UNICEF; and CADIMEK in Kananga, CADMETA in Kalemie, and CAMENEU in Ariwara are subsidized by the EU through the 9th EDF.

### **Pharmaceutical Policy, Laws, and Regulations**

Several of the pharmaceutical policies and guidelines required for good management practices have been developed and revised within the last three years. Two laws currently provide the basis for the legal framework for pharmaceutical regulation in the country: Order 27a/Hyg of March 15, 1933, on the practice of pharmacy, and the Royal Decree of March 15, 1952, on the healing arts in the DRC. In addition, several ministerial decrees have been issued in subsequent years to address specific areas related to pharmaceutical management, for example, the decrees establishing the DPM, as discussed above.

Because the laws governing the pharmaceutical sector are fairly old, dating from the colonial period, they need revision. With technical support from USAID through the SPS Program, this was done in February 2008. Some of the changes in this new law include—

- Updated definitions of pharmaceutical products and pharmaceutical establishments
- Designation of the current essential medicines procurement system, SNAME, as the national pharmaceutical supply system
- Revision and clarification of the rules on the importation and exportation of medicines
- Updating the requirements for the regulation of the pharmaceutical sector, including clarification of the definition of *Agence du Médicament* (medicine agency)
- Updated laws for the registration of medicines
- Revision and clarification of the role of pharmaceutical inspection to strengthen the enforcement of pharmaceutical regulations
- Incorporation and recognition of pharmacovigilance and rational medicine use

The revised law was submitted to the parliamentary office and is awaiting a vote by the parliament. The pharmacy board, which was involved in revising the law, was given the responsibility for following up with the parliamentary office to ensure submission of the revised law to parliament. This parliamentary vote was anticipated in 2008, but parliamentary tensions have adversely affected the legislative agenda. Although the timing is no longer clear, a vote is hoped for in 2009.

The National Pharmaceutical Policy was revised in December 2005 with support from the WHO.<sup>2</sup> During this revision process, an analysis of the pharmaceutical sector was done. The findings of this analysis mirror those of the current assessment. A five-year operational plan to help implement this policy was completed in December 2006, but its implementation has not yet begun. The reason given for this delay is lack of funding to support the implementation. Poor coordination between the DPM and the other directorates and programs of the MoH has also contributed to this implementation delay.

The National Essential Medicines List (NEML) was revised most recently in November 2007.<sup>3</sup> The first version of the NEML was developed in 1987, and earlier revisions occurred in 1991, 2001, and September 2005. The revision of the NEML is expected to occur every two or three years, and the DRC is progressing toward achieving this requirement. An ad hoc committee whose terms of reference are developed at the onset of the revision exercise revises the NEML. No standing committee is responsible for this task, and no specific requirements exist for participation or membership in the ad hoc committee. However, the selection of its members currently focuses on clinicians, managers of MoH disease programs, representatives from the DPM, and some partners involved in primary health care. No defined or written procedures guide the process of revising the NEML; therefore, the process used depends on what is included in the

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<sup>2</sup> République Démocratique du Congo. Ministre de la Santé. December 2005. Politique Pharmaceutique Nationale. Avec l'appui de l'Organisation Mondiale de Santé.

<sup>3</sup> République Démocratique du Congo. Ministre de la Santé. November 2007. Liste Nationale des Médicaments Essentiels.

terms of reference for the ad hoc committee and on the experience and expertise of those asked to participate on this committee. Disease-specific standard treatment guidelines (STGs) developed by the various MoH disease programs exist. For most of the key public health diseases (malaria, TB, HIV/AIDS, Integrated Management of Childhood Illness), these STGs have been updated to reflect current WHO recommendations. However, no single document consolidates all the disease-specific STGs into one national STG, and the assessment team was not able to obtain all the STGs to ascertain that the products included in the NEML conform to the STGs.

The regulation of the pharmaceutical sector is one of the weakest points in the system. The legal framework and the roles and responsibilities for the drug regulatory authority, which is currently part of the DPM, have been defined within the national pharmaceutical policy and pharmaceutical laws. However, the drug regulatory authority's enforcement capacity is weak to nonexistent, largely because of weaknesses in the management of the DPM and its limited budget and human resources capacity. This limited enforcement capacity contributes to the chaotic environment within public pharmaceutical supply systems and even more so in the private sector, which at this time is largely unregulated. WHO and other potential donors have shown some interest in providing technical and other support to the MoH for improving its regulatory and enforcement capacity.

## **Registration of Pharmaceutical Products**

The registration of pharmaceutical products is the responsibility of the regulatory arm of the DPM and is governed at this time by ministerial order 1250/CAB/MINIS/AJ/MS/013/2001, issued on December 9, 2001. This ministerial order and subsequent orders clarifying specific issues that have arisen with respect to the registration process constitute the only written documentation for the registration process. Those interested in registering products in the country do not have any access to any written document providing guidance on the registration process.

The registration process results in two types of registered products. New products are given an initial registration for one year. If no clinical or toxic problems related to the new product are reported during this probationary period, a full registration is given for the product that must be renewed every five years. Given the absence of a pharmacovigilance system in the country, it is unclear how much tracking of clinical or toxic effects actually occurs for new pharmaceutical products. Most likely, any new product will receive the five-year full registration at the end of the probationary period.

The process for the registration of a pharmaceutical product requires the submission of a technical dossier to the DPM together with samples of the product for laboratory testing, a registration fee of USD 375, and a laboratory analysis fee of USD 50 for each product. The technical dossier should include the following—

- Manufacturer's dossier
- Chemical and pharmaceutical documentation for the product chemical data on the active ingredient, the formulation report, the certificate of analysis, and the stability report

- Clinical evidence of effectiveness and toxicity report
- Good Manufacturing Practices certificate for manufacturer in country of origin
- Certificate of registration of product in country of origin
- Fifty samples of the product that are expected to be sold in pharmacies or stores, and two samples of the product that are expected to be sold in the hospitals
- Local quality analysis report done by a laboratory in DRC

An internal DPM ad hoc committee reviews the dossiers and makes the decision whether to accept the registration. No written documentation exists to guide this decision-making process. Registration of laboratory supplies and other medical supplies is also the responsibility of the DPM, which lacks the capacity to handle it.

No database of registered products exists, and registration records when they exist are maintained in paper files. This system makes determining which products and how many are currently registered and authorized for sale in the country difficult, thus hindering performance of the required oversight of the sale of pharmaceutical products in the country. An assessment in 2005 found that more than 1,077 medicines were registered, of which 13 were traditional medicines and 315 had the one-year provisional registration.<sup>4</sup>

The registration of products provides annual revenue for the government, approximately 123 million Congolese francs per year, which could be sufficient to meet some of the current operating costs of the DPM. Interviews with the DPM suggested that these funds are transmitted directly to the Treasury and not retained by the DPM; however, this procedure was difficult to confirm because the DPM was unable or unwilling to provide its financial records for review. Information on which products are currently registered was also not readily available at the time of the assessment.

### **Selection of Pharmaceuticals**

As previously discussed, the NEML includes the basic medicines for use in all public health facilities. As recommended, the DRC NEML uses generic names for the medicines included in the list and classifies products for use according to the level of care. Two levels of care are identified in the NEML: the health center level and the hospital level. A complete analysis of the total number of products listed in the 2007 NEML was difficult because several formulations of the same product were grouped together under the generic names in the NEML. However, the NEML listed at least 149 products for use at health center level and at least 533 products for use at the hospital level. Table 2 shows the trends in the number of products listed in the NEML.

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<sup>4</sup> République Démocratique du Congo. Ministre de la Santé. Juillet 2006. Plan Directeur Pharmaceutique National.

**Table 2. Number of Products Included in the NEML in DRC**

<b>Year</b>	<b>Hospital</b>	<b>Health Center</b>
1987	172 medicines	56 medicines
2001	387 medicines 115 medical supplies	Not applicable
2005	543 medicines 473 medical supplies	Not applicable

Source: République Démocratique du Congo. Ministre de la Sante. Juillet 2006. Plan Directeur Pharmaceutique National.

On average, the NEML should normally include 300–400 products, with 40–50 products for first-level facilities, 150–200 for second-level facilities, and 300–400 for tertiary-level facilities. The DRC NEML currently exceeds these recommended levels, and the trends demonstrated in show that each revision of the NEML has resulted in an increase in the number of products listed, suggesting that a rational process for the removal of products from the NEML may not exist. Given the large number of products on the NEML, most partners have used the NEML to develop their own essential medicines lists on which to base their procurement decisions. The USAID Project AXxes has developed its own essential medicines list, which includes 95 products it has determined cover the requirements for both health centers and hospitals in the HZs it supports (Annex 5). FEDECAME has developed a list of 100–150 products (Annex 4), consisting of products for both health center and hospital levels, that it uses as the basis for its procurements. A comparison of the essential medicine lists of Project AXxes and FEDECAME found that they had only 47 products in common, which represents approximately 50 percent of the items on each of their lists. If this pattern holds true for each donor, significant variability may exist in the medicines available in the health facilities in different HZs, despite any similarity in the morbidity patterns.

## **Quantification**

Given the fragmented nature of the DRC’s pharmaceutical system, responsibility for estimation of requirements depends on whether the partner supporting the HZ or the MoH program is following a “push” or “pull” pharmaceutical supply system. SNAME is based on a pull model; hence, the health facilities are responsible for estimating their requirements and forwarding these requirements to the BCZS for their health zone. The BCZS consolidates all the requirements for the health facilities within its zone and submits this request to the CDR. The CDR then consolidates the requirements for the BCZSs it serves and submits this consolidated request to FEDECAME. Given this system, the accuracy of the quantification depends largely on the capacity of the health facility staff to do the quantification and the resources made available to support them in this process. From the results of this assessment, quantification, particularly at the health facility level, appears to be a critical challenge and one of the main weaknesses of the procurement cycle.

Reliable estimates depend largely on the availability of accurate and reliable consumption or morbidity data on which to base the quantification. These data are currently missing and are not

being collected by the health facilities, the MoH, or most of the partners or programs interviewed during the assessment. The team was unable to collect national consumption or morbidity data for even the key diseases, and no system seems to exist at the national level for collecting and tracking these data.<sup>5</sup> The PNT is one of the few programs or partners that has been trying to collect consumption data systematically, though it indicated it has had less than a 40 percent response rate (compared to an almost 100 percent reporting rate of the epidemiological data it requires). The PNT believes that one of the reasons for this reduced response rate for consumption data is that it has not emphasized the collection of the consumption data. This will be the focus of its training in the next few months. Additionally, the PNT is considering introducing a performance index linked to the consistent reporting of consumption data that influences the level of premiums awarded to the health facility personnel by the nongovernmental organizations operating the TB programs on behalf of the PNT. Following up with the PNT in a few months to determine the success of the renewed focus on collecting consumption data would be interesting, because it may be a template for other programs or partners.

Parallel quantification exercises are performed for each donor-supported supply chain. Methods for quantifying needs vary widely across the country, depending on the requirements of the HZs' various donor partners (who assume the role of procurement agents). Even within each HZ, quantification methods may differ, depending on the requirements of vertical disease-specific programs. Overall, the absence of reliable consumption or morbidity data means that pharmaceutical supply needs are quantified based on dispensing data (at best), the popularity of the pharmaceuticals (at worst), or any "method" in between—from demographic data to availability of funds.

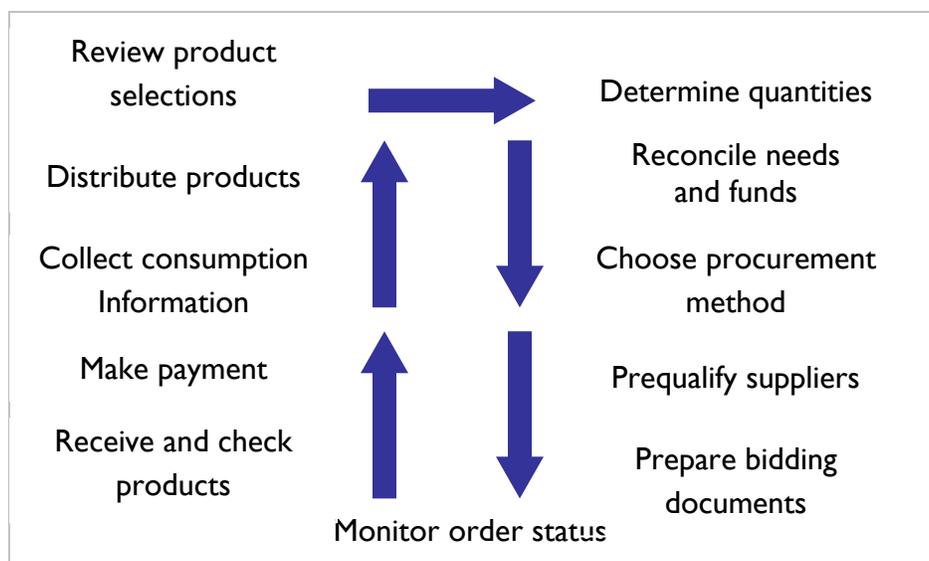
## **Procurement**

Figure 4 summarizes the pharmaceutical procurement cycle. Product selection and estimation of requirements (quantification), which have been discussed in the preceding sections, are key elements of the procurement cycle.

The procurement method selected differs according to the requirements of the various partners, although almost all of them depend on international procurements. Within the national pharmaceutical supply system, FEDECAME has the mandate to conduct all the procurements. FEDECAME is authorized to procure only products listed on the NEML, and as mentioned earlier, it has reduced the NEML to a list of 100–150 products that it actually procures. Included in this FEDECAME list are 97 high-volume products that it routinely procures. FEDECAME procurements are guided by the procedures in its handbook of procedures. This handbook was first developed in 2005 and finalized in April 2006.

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<sup>5</sup> A national health information system that may be useful in providing some of the required morbidity data is being rolled out in two pilot provinces.



Source: Management Sciences for Health.

**Figure 4. Pharmaceutical Procurement Cycle**

All FEDECAME procurements are done through open tenders, with approximately 98 percent representing international open tenders. The limited success of local manufacturers in participating in the tender process is largely because most of them have not achieved the required Good Manufacturing Practices certification. The tenders are conducted every two or three years (with deliveries scheduled three or four times a year over the two- or three-year period). The average lead time to delivery for FEDECAME is three to four months. FEDECAME uses a system for prequalifying suppliers, who are prequalified for each product for a period of two or three years. As mentioned earlier, the technical body within FEDECAME that oversees its procurements is the BCAF. This office is responsible for preparing the bidding documents for the tender and for opening and reviewing the tenders. One of the identified challenges within FEDECAME is the limited capacity of its staff in the skills related to development and assessment of tenders, including writing tender bid specifications and assessing tenders based on the overall value provided as opposed to the price quoted. Understaffing within FEDECAME may also be a contributing factor.

FEDECAME does not have a central warehouse or capital reserves; therefore, its procurements are limited to those orders received from the CDRs and for which a deposit of 30 percent of the final cost of purchase has been received from the CDRs. MissionPharma and the International Dispensary Association (IDA) are two of the most frequently used suppliers. Because of the current low volume of procurements (approximately USD 2 million per year), FEDECAME faces a challenge in gaining access to top-tier suppliers and thus is likely losing out on obtaining the highest-quality products at the best available costs. This challenge might be overcome by increasing the number of clients that FEDECAME serves as a way to increase the volume of its annual procurements. A limited list of low-volume products is procured as direct purchases outside the tender system.

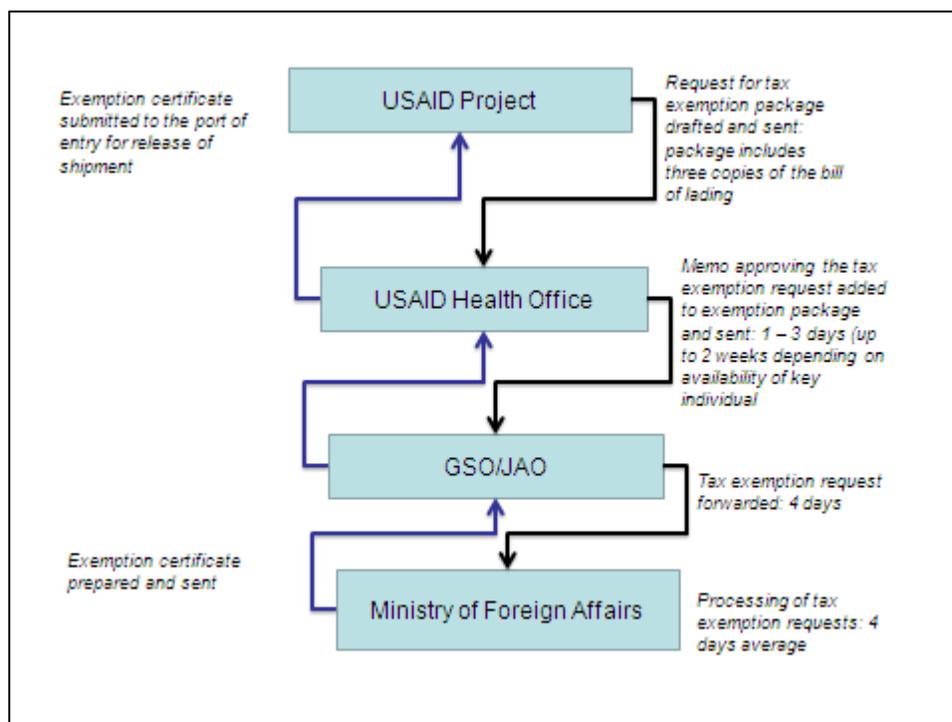
Pharmaceutical products imported for use in the public sector in DRC are not all tax exempt, and the clearance process at the ports of entry contributes significantly to the lead time for delivery of the procurements. Essentially, four customs clearance processes govern the importation of medicines and health products in DRC.

- The standard process: The default customs regime applies to all kinds of goods. It is not generally used for pharmaceutical product imports intended for use in the public sector because it does not provide any exemption from taxation.
- The taxation waiver process (the *note verbale* process): This method provides exemption from all taxes except for the 5 percent administrative tax on CIF value and all the administrative fees. The *note verbale* is available to all agencies with diplomatic status and is the process used in USAID procurements. A separate exemption has to be obtained for each individual shipment. Though the process is very simple (the process used by USAID is described below), the total lead time for obtaining a *note verbale* is fairly long (averaging three to four weeks, depending on bottlenecks both at the applicant agency's end and at the Office des Douanes et Accises [OFIDA; Customs and Excise Office]). No import may enter the country before the *note verbale* is submitted to the Customs office at the port of entry bearing the proper OFIDA seal.
- The *Enlèvement d'Urgence* procedure applies only to perishables such as vaccines and reagents. It is delivered on a case-by-case basis and allows the importer to forward the goods to their final destination without waiting for the *note verbale* to be issued. The shipment is still customs-bonded and ultimately must be cleared through the *note verbale* process.
- The *Enlèvement d'Urgence Permanent* is obtainable for medicines, health equipment, and services in a few cases. It is a blanket, multiyear partial exemption (except for the administrative tax and fees) granted by the Administrator of the General Directorate of OFIDA that allows the importing agency to bypass the clearance process and forward the shipment to its final destination without delay. FEDECAME is one of the few beneficiaries of this authorization.

Although FEDECAME is the sole or one of the few beneficiaries of the blanket multiyear waiver of importation taxes on all the products and services it procures above, it still has to pay an administrative tax and fees. Theoretically, these taxes and fees are 5 percent of the value of the imported products; in reality, they are now approximately 6.6 percent of the value of the products. This administrative tax is included in the cost of sales of the products to the CDRs. The requirement that FEDECAME pay this administrative tax is contrary to the contract the government has signed with PNAM, on behalf of SNAME, which requires that this tax be reduced with a view to eliminating it entirely for all FEDECAME procurements. PNAM has been pursuing a waiver of this tax with other sectors of the DRC government but has not been successful to date.

Donors and other MoH partners who do not procure through FEDECAME are responsible for either paying importation taxes on the pharmaceuticals they import or obtaining a waiver from

the Ministry of Finance. This waiver has to be processed separately for each shipment. Waivers for USAID-supported procurements are processed through the General Services Office of the Joint Administrative Office of the U.S. embassy in DRC. Figure 5 summarizes the process for obtaining the waiver.



**Figure 5. USAID DRC tax-exemption process**

The tax-exemption process as currently designed requires that each application for a tax exemption be submitted by the USAID project doing the procurements to the USAID Health Office for verification. The USAID Health Office then forwards the tax-exemption request package to the General Services Office of the Joint Administrative Office together with a memo that verifies its authenticity. The General Services Office forwards the exemption package to the Ministry of Finance, which is the only office authorized to prepare the exemption certificate. The entire exemption cycle, from application submission to issuance of the exemption, takes on average one month. Delays arise when the USAID Health, Population and Nutrition officer responsible for preparing the exemption certificate is unavailable but more commonly from delays in processing within the Ministry of Finance.

The USAID projects interviewed, Project AXxes and PSI, have different procurement procedures. All procurements for Project AXxes in DRC are managed internationally through IMA World Health, the prime partner. Most of the products purchased come from two main international suppliers, MissionPharma and IDA, because they have been prequalified to support IMA's procurements on behalf of Project AXxes. As mentioned earlier, Project AXxes has

developed its own list of 95 products, based on the NEML, that it procures on behalf of the HZs it supports. PSI conducts its own procurements internationally.

One of the major logistical bottlenecks for the pharmaceutical supply system is the clearance of the products at the country's traditional ports of entry. The lack of space, infrastructure, moving equipment, and tracking systems is exacerbated by the fact that some importers wait too long before paying customs duties, clearing their containers, and forwarding them inland. These conditions combine to create acute bottlenecks and long delays and add to the lead time for delivery of procured products. The phenomenon is particularly acute in Matadi, where containers intended for the interior compete for space and customs attention with imports intended for the populations of Kinshasa, Bas-Congo, and other southwestern provinces in general. In addition to these logistical challenges, governance challenges (as explained in the governance section) at the ports of entry have contributed to delays.

Two other ports of entry have become important for the pharmaceutical supply system: Goma in the east, and Lubumbashi in the south. Products that arrive in Goma are shipped via air to Kigali, Rwanda, then transported by road to Goma, or they are imported through the ports of Mombasa, Kenya, or Dar-es-Salaam, Tanzania. Products that arrive in Lubumbashi are shipped through the port of Dar-es-Salaam. Although both these ports of entry experience delays, because of the lower volumes of products they handle, their delays are not as extensive or as entrenched as those that occur at Matadi. FEDECAME already uses Goma as its port of entry for imported products intended for the eastern and southern DRC and has plans in place to use Lubumbashi when the train link with the southern part of the country has been improved. Project AXxes also uses these three ports of entry for its products. Most of the other partners and donors continue to import all their purchases through the Matadi port from where they have to be cleared and transferred to warehouses in Kinshasa for repackaging and transportation to all other regions of the country.

## **Inventory Management, Storage, and Distribution**

SNAME and all the partners and MoH programs that have developed pharmaceutical supply chains rely on private clearing and forwarding agents, and private transportation companies to transport the medicines and supplies to the depots or offices in the districts. Transportation within the country is one of the major bottlenecks for all pharmaceutical supply chains operating in the DRC. The vast and difficult geographic terrain in DRC and the lack of significant capital investment in the transportation sector for several decades cause most of the transportation challenges. Road transportation is limited, with no modern road networks connecting the eastern and western parts of the country. Heavy rains that are common in the country regularly wash out bridges, where they exist, which can cause delays of several weeks while repairs are done. A slow and unreliable water transportation network exists via the Congo River and its confluents. Boats, mainly pirogues that transport people and products along the Congo River, exist, but they do not operate on any regular schedule and will usually depart only when they are full, which can result in delays of several weeks to months while they wait for additional cargo or passengers. The train network is practically nonexistent although there are currently plans to revitalize the rail link connecting Lubumbashi with other towns in Kasai and the southern tip of the country.

Given these challenges, the primary mode of transportation for pharmaceutical supplies after their arrival at the ports of entry is via air. Because relatively few airlines for a country of this size operate routes in DRC, ongoing challenges arise here. The airlines that do exist face several problems, including poor financial stability and less-than-stellar safety and customer-service records, and are generally expensive and unreliable. None of the airlines is equipped to handle pharmaceutical products, particularly those that require cold-chain support. Additionally, in an attempt to maximize their returns, the airlines will usually not ship a package until they have filled their cargo holds or have a guarantee of a full load at the final destination for the return trip. As a result, the smaller medicine packages compete with bulkier cargo for planeloads and may sit in the airline's warehouse for several weeks if the airline does not have a full load.

Most of the pharmaceutical supply systems use some three or four main private transportation companies to move their products within DRC. AGETRAF and GTMA are two of the largest.

AGETRAF is the largest private sector transportation company operating in the country, but its experience and focus in the past have been on international transportation. It has begun to move aggressively to meet the gap that has resulted from the poor local transportation options for pharmaceutical suppliers and has recently been contracted to transport the products procured by the GFATM and its Principal Recipient, the United Nations Development Programme. AGETRAF has also delivered insecticide-treated nets nationwide on behalf of the PARSS project. As part of its efforts to meet the needs of United Nations Development Programme contract, AGETRAF has renovated a warehouse in its Kinshasa depot to include a 465-square-meter cool room that is maintained at 18°C to 21°C and a cold room that is maintained at -2°C to 8°C. AGETRAF has purchased 28 × 14 packaging that meets IATA standards for the transportation of infectious products and a refrigerator that can be attached to an airplane or a vehicle that can maintain cold temperatures for 72–96 hours without electricity. AGETRAF has also hired a pharmacist and a pharmacy assistant to manage this renovated warehouse. However, a complaint that arose during the assessment is that AGETRAF can be unresponsive to pharmaceutical clients. Largely attributable to the volume of pharmaceutical supplies shipped by AGETRAF, which is several times less than the volume of other products, the situation does not create any incentives for the company to prioritize public health clients over clients shipping larger volumes.

GTMA has been providing local transportation within the DRC for longer than AGETRAF. It has not invested in, nor does it plan to invest in, a cold-chain support system, however. When the need arises to transport products requiring a cold chain, GTMA uses the *Enlèvement d'Urgence* procedure described earlier to clear the products from the port of entry and try to send them to their final destination within 24 hours. Where this procedure is not possible, GTMA refers its clients to Médecins San Frontières, which has cold-storage facilities in the Kinshasa area that may be available to meet clients' short-term needs.

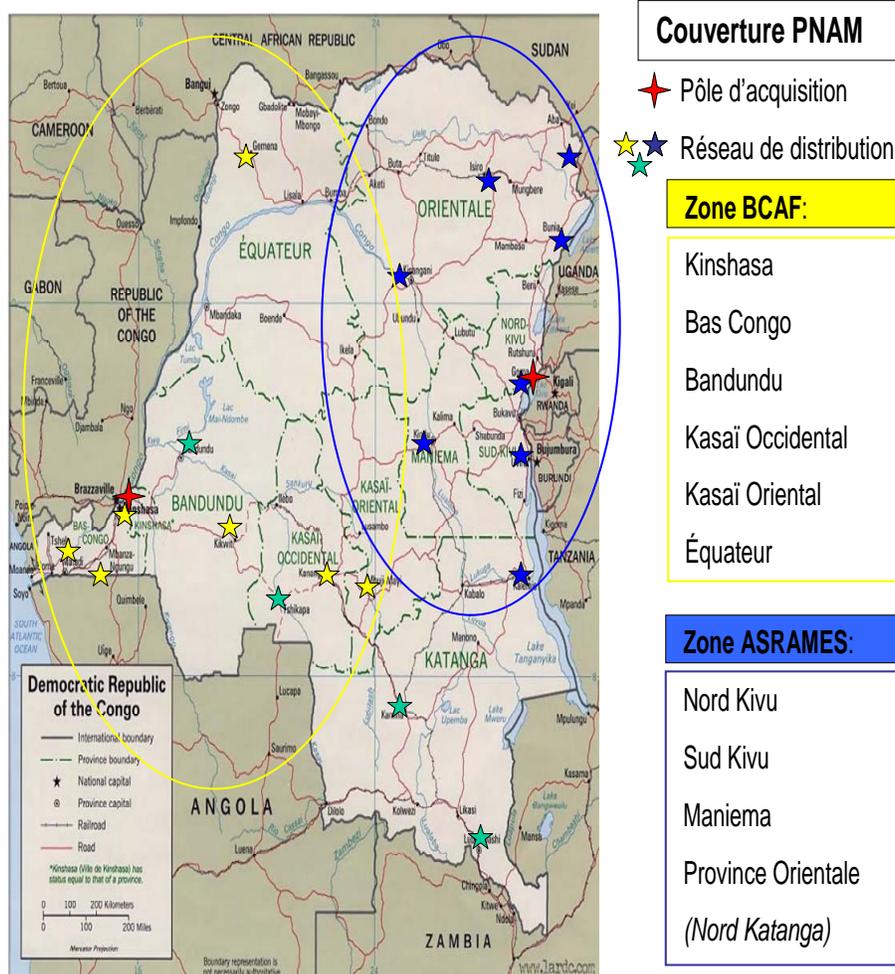
Project AXxes uses three main transportation companies: Gecotrans, used most commonly for transporting containers; SOSAR, used for airfreight; and GTMA. Project AXxes does not use AGETRAF because of its unresponsiveness. Other transportation companies mentioned by the partners interviewed include Delta Express and Meribel.

Some of the partners, including the GFATM procurement unit, have contracted the transportation companies discussed above to ship products to the health facility or BCZS level. Several others, including SNAME and Project AXxes, require the private transport companies to deliver their products only to the regional depots or CDRs. The BCZS is then responsible for collecting or arranging for the collection of the supplies from these regional depots and delivering them to the health facilities in their zone. Project AXxes has provided the BCZSs in the HZs it supports with motorcycles and, in some cases, with cars to help the BCZSs meet their transportation needs. Where no support exists, the BCZS and health facility staff rely on available public transportation, which is irregular, is unreliable, and limits the quantity of products that can be transported.

The planned distribution network from the ports of entry to the CDRs for SNAME is represented in Figure 6. The blue stars represent the locations of CDRs served through the Goma port of entry, the yellow stars are for CDRs served through the Matadi port of entry, and the green stars represent the CDRs that will be served by the Lubumbashi port of entry.

All the pharmaceutical supply chains operating in the country depend on a network of private depots that the partners either lease and operate themselves or contract to provide warehouse facilities for their products. These depots are of varying quality and depend in large part on the standards and expectations of the partner or client. SNAME has developed specific storage standards that depots interested in becoming CDRs must meet. The two CDRs visited during this assessment were both very well run and well organized, with the appropriate storage conditions, including shelving and pallets, temperature control and tracking, security, cleanliness, and designated repackaging areas. Project AXxes uses the CDR system for the storage and distribution of its purchases. It has negotiated contracts for the warehousing and management of the products with individual CDRs in the regions where it is providing support and ships its procurements directly to these CDRs. The BCZSs in the AXxes-supported HZs are responsible for picking up the supplies for their health facilities from the CDRs, and the health facilities then pick up their supplies from the BCZSs. Because the BCZSs do not have warehouses, ideally the health facilities should pick up the products they purchase almost immediately. This ideal is not usually met, however, and the BCZSs in many cases have to store the medicines for several weeks in designated areas in their offices that are not usually adequate for storing medicines. The two BCZSs visited during this assessment were both facing this challenge.

The SNAME standards for CDRs require the purchase and use of inventory management software. APISOFT is the currently recommended inventory management software package. Use of the same software allows the CDRs to link with the FEDECAME system via the Internet and improve their communication. Seven CDRs are currently linked to the FEDECAME system. The cost of APISOFT (€5,000) has delayed implementation by other CDRs who are interested in using it. Two CDRs affiliated with SNAME (ASRAMES and CAMEKIS) use EXACT software, which they had installed before becoming part of the SNAME system. The other CDRs within SNAME are currently using Excel while trying to raise the required funds to purchase the APISOFT software. Outside the SNAME system, the use of computerized inventory management systems is not required or standardized.



Source: PNAM.

Figure 6. SNAME distribution system

## Quality Assurance Systems and Pharmacovigilance

The quality assurance systems in the DRC are weak. There is no WHO-certified testing laboratory though the government has identified four private sector laboratories that should be used for testing all imported pharmaceuticals.

The quality assurance process as currently defined begins at product registration when a sample of the product to be registered is included in the registration packet. This sample is tested at one of the four approved laboratories to confirm that it is consistent with the test results included in the registration package. At the time of importation of the medicines, a sample from each batch is collected for testing at the Office Congolais de Control laboratory (a government-run laboratory that tests all imports). Given the volume of products that this laboratory tests and its limited capacity, products are often allowed out of the port and into the general market before completion of the testing. Consequently, any problems identified after the testing is completed would theoretically require that the product be recalled from the market, something that is

currently almost impossible to do with the poor communication system and the absence of a pharmacovigilance system. This issue is particularly problematic within the private sector.

Within SNAME, a clearly defined quality control system is in place for the products it procures and distributes. This system begins with the prequalification of all suppliers by FEDECAME. The prequalification is a document-based analysis (that includes documents detailing the results of the quality analysis) that is done every two to three years. All procurements are made from prequalified suppliers only. Samples of all lots from the shipments are collected at the port of entry and sent to the Office Congolais de Control laboratory for analysis (accompanied by the certificate of analysis). After reception and once the products are distributed, any subsequent testing is done at the University of Kinshasa laboratory, which is one of the government-approved laboratories. Almost all those interviewed indicated they use the University of Kinshasa lab for any quality assurance analysis needed. The assessment team was unable to visit this laboratory to assess its technical assistance needs; however, the reports from those interviewed who use this laboratory suggest it is overwhelmed because the demand for its services currently exceeds its capacity.

Within the public sector, the weakest link in assuring the quality of the products distributed is at the regional and peripheral levels. The unreliable transportation and distribution systems and poor storage facilities at these levels make ensuring the quality of products impossible after they are shipped from the port of entry. Within the private sector, the weakness of the regulatory enforcement arm of the DPM means very little, if any, oversight occurs of the products for sale, and no postmarketing quality surveillance or quality assurance systems are in place. The size of the DRC and the multiple ports of entry in use by the private sector, and now by the public sector, may require more than one reference laboratory that meets quality assurance needs.

## **Pharmacovigilance**

Currently no pharmacovigilance system exists, although the MoH has signed a ministerial decree creating a national system, and plans have been developed to guide the implementation of the system. The GFATM and WHO both have shown an interest in supporting this process, but what the extent of their assistance will be is not yet clear. As previously mentioned, the pharmacovigilance system is a crucial component of the registration process and a component of an effective postmarketing surveillance system because it can be the front line for identifying potential problem medicines in the market. With the introduction of many new medicines for treatment of AIDS, TB, and malaria that have not been used on a wide scale in the country, an effective pharmacovigilance system is important to ensure that no adverse effects arise that can affect the acceptability of the new products.

## **Pharmaceutical Management Information Systems**

No functional, integrated health information system exists, as reflected by the difficulty in obtaining any reliable morbidity and mortality data. Some of the programs, particularly the PNT, have established systems to collect epidemiology data relevant to their programs. No system exists for collecting relevant pharmaceutical management information although the DPM and PNAM both expressed an interest in developing one. PNAM currently collects specific information from its affiliated CDRs. The information collected includes—

- Management information
  - Number of structures supplied
  - Number of orders received
  - Number of unfulfilled orders
- Distribution information
  - Availability of a specific set of tracer medicines
  - Inventory management information, including a comparison of the data obtained from APISOFT, invoices, and stock cards
  - Daily temperature tracking data
- Financial information
  - Value of products sold
  - Evolution of cost-recovery process at CDR

This PNAM system, though currently targeted to meet its needs, could potentially form the basis for a national pharmaceutical management information system (PMIS). One key data point not being collected is the actual consumption data.

As previously mentioned, the PNT is one of the few programs attempting to collect consumption data. Nationally, the only other consumption data that should be collected is what is included in the nonfunctioning health management information system (HMIS), which is mainly a minimal list of basic medicines for treatment of early childhood illnesses. This list needs to be updated to comply with the current changes in treatment recommendations.

At the peripheral level, that of the BCZSs and the health facilities, forms for data collection existed in the HZs visited (these were all Project AXxes HZs and may not reflect the situation in other HZs). Although these forms exist, those who are required to fill them at the facility level, or collate them at the BCZS level, are not necessarily doing so.

## **Financing, Sales, and Cost-Recovery**

The DRC government provides very little budgetary support to the health sector. Table 3 summarizes the evolution in the state budget allocated to health. Although the total amount of money allocated to health has increased, the proportion relative to the total budget has decreased. In 2008, 2.5 percent of the state budget (approximately USD 61,504,022) was dedicated to the

health sector, of which, based on past experience, only 50 to 60 percent (approximately USD 36,902,413), that is, USD 0.62 per person, will actually be finally released/executed. About 80 percent of the funds allocated by the state is retained at the central level of the health system and mainly contributes to operating costs, and in particular the salaries, of the staff at the central level.

Although a portion of the health budget may be reserved for procurement of pharmaceutical products, in reality none of the funds is currently used to support either the purchase or the subsidy of pharmaceutical products for the public sector. Because of this limited government contribution, the DRC public health system, and in particular the pharmaceutical supply system, relies on a cost-recovery model, though it currently depends largely on the subsidies from donors.

**Table 3. Evolution of the Budget Allocated (Congolesse francs), Ministry of Public Health DRC, 2003–2007**

	<b>2003</b>	<b>2004</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>
Total country budget	334,629,891,724	528,333,000,000	806,169,429,000	1,039,561,000,000	1,370,309,606,010
Health budget	16,394,063,465	28,671,595,376	35,936,413,659	41,848,168,202	49,609,895,796
Percentage allocated to health	<b>4.90%</b>	<b>5.43%</b>	<b>4.4%</b>	<b>4.03%</b>	<b>3.62%</b>
Expended amount	9,012,975,111	9,355,927,078	19,676,548,930	18,756,844,993	
Rate of expenditure	<b>54.98%</b>	<b>32.63%</b>	<b>54.75%</b>	<b>44.82%</b>	

*Source:* République Démocratique du Congo. Ministre de la Sante. Programme Nationale d'Approvisionnement en Médicaments essentiels. Juillet 2008. Plan Strategique 2008 - 2012. Avec l'appui de USAID et SPS/MSH.

As discussed earlier in this section, FEDECAME and the CDRs do not have any capital reserves and rely on the funds generated from the cost-recovery process to finance their procurements and operations. This situation creates a delay when procuring because procurement has to be done on a cash basis. FEDECAME cannot place any orders until it has received the 30 percent advance payment the suppliers require. Any additional capital investments or procurements require the support of a donor. At this time, FEDECAME is unable to maintain any capital reserves or sufficient levels of security stock. To address this problem, the BTC has offered to provide some funds (USD 600,000) in the next financial year to create a financial reserve for FEDECAME. One of the main threats to the financial sustainability of SNAME at this time is that the main donor supporting the system since its inception in 2004, the EU, will be phasing out its support, and no substitute has been identified yet. In addition to providing technical support for strengthening FEDECAME, the EU, through the 9th EDF, has been the one donor that makes all the procurements for the HZs it supports through SNAME and is thus the major contributor to the cost-recovery funds supporting the system.

One of the key problems with the cost-recovery system at this time is that the MoH has not specified standardized margins for each level of the health sector, so each program or donor is free to establish its own margins or subsidies to meet its own objectives. This piecemeal approach results in a situation where neighboring HZs could theoretically be providing identical products at different prices to the end users, including some HZs where all the products are provided free. This price disparity contributes to some of the governance problems that are creating a challenge in managing the pharmaceutical system.

## **Governance**

Although they arise largely outside the pharmaceutical system, governance issues present the most challenging threats to management of the pharmaceutical system. A general sense of impunity exists at all levels of society; many within the system do not feel accountable to anyone other than their direct financial donor and in some cases the local “power player.” They also do not appear to be accountable to the communities they serve. One of the key specific contributors to the governance challenges within the pharmaceutical sector is nonpayment of salaries, particularly of staff working at the health facility level. Some donors provide a *prime* (bonus) to supplement the salaries of the staff in the HZs they support, but others, including USAID, which by law cannot provide direct salary support to government employees, do not provide any salary supplements (*prime*). Because these are the same staff responsible for managing the finances of the health facility and the cost-recovery funds, the likelihood of misappropriation of funds, even by those inclined to be honest, is greatly increased. Project AXxes has identified this as a challenge it faces in the HZs it supports. Although the health facilities in the Project AXxes–supported HZs are required to submit all the money they generate from the sale of medicines to the BCZSs, they are not doing so. The BCZSs receive on average less than 50 percent of the funds they should be receiving from the HZs. In addition, anecdotal evidence suggests that some staff in the HZs have decided to supplement the money they receive by buying and selling some pharmaceutical products from the private sector instead of CDRs. They do so without a paper trail, making it difficult for supervisors to monitor the actual sales and receipts in the health facilities.

At the regional and central levels, SNAME has developed fairly transparent and accountable systems. FEDECAME publishes management reports every three months that include FEDECAME’s accounts, and this information is shared with the oversight committee a week before the quarterly meetings. These documents are also available for review by interested partners and others. FEDECAME and the CDRs visited during this assessment were the only ones who readily provided a copy of their recent accounts and reports to the team for review. It is hoped that this level of transparency will continue even after the involvement of the 9th EDF in support of the system is phased out.

## OPTIONS ANALYSIS: SUGGESTED INTERVENTIONS

The most effective support USAID and other donors could provide to the pharmaceutical supply system in the DRC would be to begin the process of fully integrating the procurement and distribution of the pharmaceutical products it procures into the national system. This integration would allow USAID and SNAME to benefit from the economies of scale that would emerge as the volume of products that pass through SNAME increases and would provide opportunities for USAID to contribute to the sustainable strengthening of the pharmaceutical supply systems in the country.

### Integration of Parallel Procurement and Distribution Mechanisms into SNAME

This integration process may take at least three different approaches.

#### 1. *Direct Delivery to the CDRs*

Under this option, USAID would retain responsibility for procurement and delivery of pharmaceutical products directly to specific CDRs, thus bypassing the central levels of SNAME. Distribution from the CDRs to the peripheral levels would follow the existing SNAME mechanisms. This model would require that USAID or its partners identify the CDRs they wish to work with and negotiate separate contracts with each. This model is what the Project AXxes currently uses.

Advantages:	Under this model, USAID retains control over the actual procurement process and is better able to control the quantity and quality of the products delivered and the timeliness of their delivery.
Issues to Consider:	USAID and its partners retain responsibility for shipping and transportation of the products from the suppliers through the ports of entry to the CDRs. They also retain responsibility for clearing the products at the port of entry and for obtaining the required tax-exemption waivers with each shipment.
Potential Timeline:	This alternative is similar to what is already occurring through Project AXxes and would be an alternative that could commence almost immediately because agreements are already in place with some of the CDRs that could provide a template for future agreements.
Cost Components:	<i>Staff time:</i> To develop and negotiate contracts with CDRs, quantify requirements and conduct the procurements, monitor the transportation and delivery to the ports of entry, clear the products from the ports of entry, develop a distribution plan and ensure delivery to health facilities in accordance with the plan, monitor and evaluate performance of the CDRs under the signed contracts.

*Transportation:* Shipping costs and local delivery costs to health facilities.

*Contract Fees:* To CDRs to store and manage the products and to ensure their distribution to BCZSs and health facilities. Currently this fee is approximately 7 percent of the value of the goods as negotiated by Project AXxes. The current fees charged by the CDRs are not standardized and will have to be negotiated with them.

## **2. Direct Delivery to FEDECAME**

Under this option, USAID would negotiate a contract directly with FEDECAME to use its storage and distribution systems to get the products out to the CDRs. USAID would retain responsibility for procurement, shipping to, and clearance from the ports of entry, including obtaining the tax exemptions. FEDECAME would manage the products after they have been cleared and distribute them to the CDRs in accordance with the agreement with USAID.

**Advantages:** Because USAID's responsibility ends at the port of entry after customs clearance, this option frees USAID and its partners from involvement in storage and transportation of the products once they are in the country. In addition, USAID or its partners would only need to negotiate and sign one contract with FEDECAME as opposed to multiple contracts with individual CDRs.

**Issues to Consider:** USAID would have no direct control over the products once they enter SNAME. Even though FEDECAME is in the process of opening a warehouse in Kinshasa to store the security stock it wants to purchase, this option may require FEDECAME to store products in warehouses in Kinshasa or Matadi before shipping the goods to the respective CDRs if transportation arrangements are not well coordinated between USAID and FEDECAME before arrival of the shipments. This situation could potentially add a new level to the national distribution system. Whether FEDECAME would be willing to pursue this option is not clear.

**Timeline:** The timeline would be largely determined by negotiations with FEDECAME and how long obtaining approval for this option would take. Discussions with FEDECAME could begin immediately.

**Cost Components:** *Staff time:* To develop and negotiate contracts with FEDECAME, quantify requirements and conduct the procurements, monitor transportation and delivery to the ports of entry, clear the products from the ports of entry, and evaluate performance of FEDECAME under the signed contract.

*Transportation:* Shipping costs to the points of entry.

*Contract fees:* The fees due to FEDECAME to manage the products after arrival at the ports of entry and ensure their distribution to the CDRs. No

standardized rate exists currently; it will depend on the negotiations with FEDECAME.

### **3. Direct Purchase by FEDECAME**

Under this option, USAID would contract with FEDECAME to procure and distribute the pharmaceutical products needed. FEDECAME would need to be approved as a recipient of U.S. funds for the purpose of procuring health commodities.

**Advantages:** This option uses all the levels and capacity of SNAME, would likely yield the greatest long-term system-strengthening benefits, and is consistent with the aim of developing a fully integrated, sustainable national pharmaceutical supply system. Because the EU is already pursuing this model, a template exists for the negotiations with FEDECAME.

All commodities procured with U.S. funds through FEDECAME will benefit from the Permanent Clearance waiver granted to all FEDECAME imports, thereby freeing USAID from the tax-exemption waiver process. This model provides an opportunity for USAID to become more involved in SNAME's functioning, particularly for providing the additional impetus for the continued transparency of the system (especially critical if the EU withdraws its support).

**Issues to Consider:** No USAID precedent exists at this time for the development of the contract with FEDECAME although a similar approval process is well under way in Rwanda with CAMERWA. This option would likely require extensive discussions within USAID and would likely result in a lengthy approval process. A significantly higher level of risk exists because USAID would not have direct control over any part of the procurement process. A technical adviser would likely need to be installed within FEDECAME to provide the needed oversight.

**Timeline:** Several months to several years depending on the approval process (the increased perception of risk and the potential need to perform multiple audits to alleviate that risk).

**Cost Components:** *Staff time:* To develop and negotiate contracts with FEDECAME and to monitor and provide technical support to it as it manages the procurement and distribution process.

*Contract fees:* The fees due to FEDECAME to manage the procurement of the products and ensure their distribution to the CDRs. No standardized rate exists currently; it will depend on the negotiations with FEDECAME.

## **Conclusion**

Given the strengths and weaknesses of these three options, USAID may be better advised to take a two-step approach in achieving this integration. Option 3 is the ultimate objective but would require extended negotiations to be consistent with USAID requirements; therefore, although conversations and preparation for option 3 could start immediately, option 1 would be the preferred course of action in the interim. The final cost for implementing any of these options ultimately depends on how many staff members from USAID or its contractors are seconded or assigned to FEDECAME or SNAME to assist in implementing this integration.

## **Strengthening USAID's Capacity to Oversee and Support All the Mission's Pharmaceutical-Related Activities**

To strengthen the Health Team in its ability to manage its multiple pharmaceutical-related efforts in support of its programs, the USAID advisor on the team recommends the creation of a full-time Commodity Manager position within the Mission's Health Team. The Commodity Manager should ideally be a pharmacist. Alternatively, he or she would have a medical or public health background. In any event, the Commodity Manager should be technically sound in supply chain management. The Commodity Manager's roles would include management of all USAID pharmaceutical-related activities, from overseeing the USAID partners involved with pharmaceutical procurement and distribution to liaising with the SNAME to advocating with the MoH and other donors for the advancement of a more effective national pharmaceutical system in the DRC.

## **Technical Support to Address Governance Challenges in the Pharmaceutical Sector**

### ***Rationale***

As mentioned in the preceding Summary of Findings, the governance challenges identified during the assessment were multisectoral in origin and scope. Therefore, beginning to address them will require a multisectoral approach and extended periods of advocacy to involve all necessary sectors in changing the prevailing culture.

### ***Issues to Consider***

- **Impact of financial challenges:** The governance challenges and the financial challenges are interrelated, and their long-term resolution depends on the willingness and ability of the government and its partners to address both. At the health facility level, the lack of pay for the nonmatriculated staff and the poor pay of the other staff all contribute to the inappropriate management of finances that appears to be prevalent there.
- **Willingness and interest on the part of the government to address governance challenges:** Without unambiguous support by the government in addressing the governance

challenges—and given vested interests of several groups of people, both within and outside the government in maintaining the status quo—convincing others within the pharmaceutical sector to become fully invested in addressing these challenges will be difficult.

- **Impact of external parties on governance challenges in DRC:** To what extent can those in the international community, who represent the major contributors to the pharmaceutical sector in DRC, contribute to addressing the governance challenges seen in the country? How can these external partners be incorporated in a process for changing the prevailing environment in the country?

### ***Key Activities (with Approximate Timelines for Implementation)***

- Identify partners involved in promoting good governance in the health and other sectors in DRC, both within the country and external to the country, to develop a multisectoral approach to address the good governance challenges identified (6–12 months).
- Consider convening an international committee of donors providing pharmaceutical supplies or technical assistance to DRC to develop a unified plan of action for addressing the governance challenges in the country (6–12 months).
- Develop and implement a national ethical framework. This activity will require advocacy and cooperation of MOH, other DRC government sectors, and local pharmaceutical sector partners (2–5 years).
- Review DRC's laws and MoH regulations to ensure they incorporate good governance policies (1–3 years).
- Strengthen the regulatory and enforcement capacity of the DPM as part of the restructuring of the DPM (2–3 years).

## **Technical Support to Address Financing Challenges in the Pharmaceutical Sector**

### ***Rationale***

As discussed in the Summary of the Assessment Findings, the lack of financial support and the reliance on cost-recovery and donors to finance the purchase of pharmaceuticals and the operations of the pharmaceutical system pose a real threat to health system functioning and the overall sustainability of the pharmaceutical system in the country. Developing a consistent and transparent financing system for the pharmaceutical sector is therefore critical to its functioning. The limited information on financial flows within the pharmaceutical system was one of the main challenges of the assessment, making it difficult to recommend specific activities or interventions to address any problems that may exist. Additionally, because most of the pharmaceutical systems are based on a cost-recovery model, ensuring that those who are responsible for handling the funds generated from the sales of the pharmaceutical products are well trained and are paid regularly a living wage is critical to its success.

### ***Issues to Consider***

- **Impact of governance challenges:** The relatively poor record-keeping practices at all the health-system levels, which partly result from the lack of desire by the staff at these levels to open up their financial transactions to outside review, makes providing appropriate oversight of their finances difficult and presents an additional challenge for implementing any of the potential interventions.
- **Impact of human resources challenges:** No specific standards exist for those who are hired to manage the sales of medicines at the health facility level and the proceeds that arise from those sales. Because most of the staff at the health facility level are also considered to be part of the nonmatriculated cadre of MoH staff, they are the least likely to be receiving regular salaries from the government. USAID regulations do not allow the use of U.S. government funds to pay the salaries of MoH staff. Other donors do allow this supplement, which has created the expectation on the part of MoH staff that this should be the case for all donors.

### ***Key Activities (with Approximate Timelines for Implementation)***

- An assessment of the financial flows through the pharmaceutical system with recommendations on how to improve efficiencies and plan for sustainability of the pharmaceutical system (6–12 months).
- Development and implementation of a standardized financing policy for use in all HZs to address the disparities that arise from the varying practices of different donors. This activity will depend on the results of the assessment of the financial flows and should include issues related to ensuring financial access and meeting operating costs of the health facilities, BCZSs, CDRs, FEDECAME, and the DPM. Implementation of this policy will require collaboration with other partners and the MoH at the central level (1–5 years).
- Pilot the use of performance-based financing to provide additional incentives for those working in the public health system. This activity may include incentives for FEDECAME and CDRs to meet specific procurement, distribution, and management targets; incentives for provincial and district staff to meet specific training, supervision, and management targets; and incentives for BCZS staff to meet specific quantification, ordering, management, and cost-recovery targets. The assessment of financial flows would also inform the development of this performance-based financing plan (1–5 years).
- Training health workers in good financial practices, bookkeeping, and maintenance of financial records. This activity can be incorporated into the other leadership and management or pharmaceutical management trainings (1–2 years).

## Strengthening Pharmaceutical Laws, Policies, and Regulations

### **Rationale**

Although several of the laws and policies necessary for good pharmaceutical management have been developed or updated within the last three years, their implementation has largely not yet occurred.

### **Issues to Consider**

- **Financing challenges:** One of the reasons for the delayed implementation of the revised policies has been the absence of dedicated funds to finance the operations of the DPM. The development of a financing policy for the pharmaceutical sector should include a component to address the long-term financing of the operations of the anticipated *Agence du Médicament* (Medicine Agency).
- **Involvement of the private sector:** Many of the challenges related to regulation of the pharmaceutical sector arise from the private sector. A systematic attempt is needed to engage them in developing and planning for the implementation of the new or revised policies and regulations.

### **Key Activities (with Approximate Timelines for Implementation)**

- Develop procedures for the regular review and updating of the NEML and its dissemination: this activity includes written processes and procedures for updating the NEML, and development of an NEML revision committee with defined terms of reference for its operation (1–2 years).
- Develop a streamlined, document-based or computerized system for registration of pharmaceuticals: This activity includes development of written procedures for the registration of pharmaceuticals and development of a searchable database of registered products. It should also include procedures for managing the funds generated from the registration process (1–5 years).
- Overhaul the DPM to strengthen regulatory division: As recommended in previous evaluations of the DPM, the DPM may need to be reorganized into an independent parastatal *Agence du Médicament* (Medicine Agency) with defined terms of reference, independent financial control, and independent, merit-based hiring practices to achieve the objective of strengthening the regulatory practices of the division. This change may begin to address some of the human resources, governance, and financial challenges that currently hamper the regulatory activities of the DPM (3–5 years).

## **Strengthening Capacity of Health Workers in Pharmaceutical Management**

### ***Training in Leadership and Management***

**Rationale:** One of the main weaknesses identified during the assessment was the absence of real leadership on the part of the DPM and other MoH divisions responsible for oversight of the DRC's pharmaceutical system. As part of the process of improving this oversight, ensuring that those who are responsible for running these organizations have improved leadership and management skills will be useful to assist them in providing this oversight.

#### **Issues to consider:**

- **Who within the MoH should receive this training:** Employees of the DPM (or its alternative at the central level), PNAM, and FEDECAME are obvious candidates; the provincial and district medical and pharmaceutical officers are other potential candidates for this type of training.
- **What type of training methodology to use:** Use of virtual and group-based leadership and management training methodologies should be explored. These methods provide an opportunity for ongoing training and reduce the requirement for off-site workshops that tend to be more expensive to organize and are not necessarily conducive for ongoing training.
- **Tools and materials:** Although several tools and training materials exist for training health workers (including several tools that have been developed by Project AXxes, SPS, and other partners), these materials will need to be reviewed to make sure they cover all the required areas and are suitable or can be adapted for a training-of-trainers (TOT) program.

#### **Key activities (with approximate timelines for implementation):**

- Review job descriptions or officeholder terms of reference for the DPM and divisions of the MoH responsible for pharmaceutical management, where they exist, to clarify roles and responsibilities and identify candidates for training or group allocation (2–6 months).
- Hold a meeting or brief workshop to meet with potential training candidates and other partners to brainstorm on major leadership and management training needs (1 day).
- Develop written job descriptions for key MoH central-level personnel responsible for pharmaceutical management (6–12 months).
- Develop or adapt training materials to meet group training needs (6–12 months).

### ***Training in Pharmaceutical Management and Follow-up Supervision***

**Rationale:** The health workers, particularly those at health facility and BCZS levels, form the foundation of the pharmaceutical supply system; yet they are the ones with the least knowledge and understanding of pharmaceutical management principles and practices. This lack of knowledge is reflected in the inadequate estimation of requirements for procurement of pharmaceuticals, poor purchasing decisions, poor financial management, and nonexistent

consumption tracking seen at these levels, all of which affect the entire pharmaceutical system. A need exists to train the health workers responsible for managing medicines on all aspects of pharmaceutical management with an emphasis on the following areas—

- Quantification, including the appropriate data to use when estimating requirements, the appropriate methods for quantification, and the appropriate methods for the reconciliation between requirements and funds available for purchasing
- Procurement and making appropriate purchasing decisions
- Inventory management, including appropriate storage and warehousing, management of security stocks, management of expired stock and close-to-expiry stock, proper record keeping, and management of donated products
- Information collection and data management and use, including tracking consumption data, managing epidemiological data, and using consumption and epidemiological data to support the estimation of requirements and procurement decisions
- Rational prescribing and dispensing, including the importance of compliance with STGs and the potential cost savings that may accrue from following the treatment guidelines

In addition to training, regular and consistent supervision of health workers is essential to reinforce the messages from the training and ensure that those trained are applying what they have learned in their day-to-day activities.

**Issues to consider:**

- **Training methodology:** Given the number of HZs that USAID supports, use of cascade training as part of this capacity strengthening may be the most reasonable and cost-effective option. It would require developing a cadre of trainers at the regional and district levels who would be responsible for the training and follow-up supervision at the BCZSs and the health facilities under the supervision of the USAID contractor or partner. Selection of members of the provincial and district medical and pharmaceutical offices as trainers responsible for implementing the cascade training would have the advantage of ensuring the training of the health workers in pharmaceutical management at the intermediate levels of the health system.
- **Challenges:** Identification of appropriate trainers to participate in the TOT; long-term availability and support to the trainers to conduct the training sessions and perform ongoing supervision; maintaining quality of training sessions held without direct supervision of the technical experts; resources for carrying out post-training supervision.
- **Tools and materials:** Although several tools and training materials are available for training of health workers (including several tools that have been developed by Project AXxes, SPS, and other partners), these materials will need to be reviewed to ensure they cover all the required areas and are suitable or can be adapted for a TOT program.
- **Timeline for activities:** These activities can begin immediately.

**Key activities (with approximate timelines for implementation):**

- Identification of the geographic scope for the training (2–6 months)
- Development of a training plan and schedule, including a plan for post-training supervision (2–6 months)
- Identification of suitable candidates for the TOT (2 months)
- Development of the TOT materials (2–6 months)
- Training (1–2 years)

**Technical Support to Address Key Pharmaceutical Management Challenges**

***Strengthening Quantification, Procurement, Distribution, and Inventory Management Practices***

**Rationale:** Poor quantification, procurement, distribution, and inventory management practices, particularly at the health zone and health facility levels, are all contributing factors to the nonavailability of required pharmaceutical products.

**Issues to consider:**

- **Human resources challenges:** Lack of standardized requirements for those hired to manage medicines at the BCZS and HZs. Training may address some of the gaps in knowledge in pharmaceutical management.
- **Poor infrastructure:** This issue contributes particularly to the poor transportation and storage of the pharmaceuticals. Addressing these challenges would require inputs from other sectors of the government.
- **Reliance on noncomputerized systems for inventory management:** This issue impedes creation of integrated ordering and consumption tracking systems, which currently use paper-based registers and ledgers that are not always available. It also requires that consumption and stock records be compiled manually, which is time-consuming and requires incentives for the health workers to perform accurately and on time.
- **Nonexistence of a PMIS:** Information required for quantification and procurement are managed in an ad hoc manner, if at all, and no person or organization had been identified as responsible for tracking or managing this information.

**Key activities (with approximate timelines for implementation):**

- Review, adapt, or develop required tools and materials to support pharmaceutical management at all levels of the health system (6–12 months).
- Provide training in pharmaceutical management (detailed in previous section) (1–2 years).

- Form quantification committees with the mandate to review and standardize quantification and check that it is consistent with epidemiologic trends. These committees should be formed at the BCZS level, under the guidance of the provincial or district pharmaceutical office, and at the central level under the guidance of the DPM or similar authority (1–2 years).
- Explore development of pooled transportation of pharmaceutical products. While moving toward integration of the parallel procurement systems into SNAME, as an interim cost-saving measure the various partners should explore the possibility for pooling their shipments to the HZs to reduce delays and additional costs that arise from shipping smaller packages (1–2 years).
- Provide training to improve skills of procurement agents at central level in negotiation, contract development, tender development, and assessment of tenders to improve their ability to extract maximum value from their contracts (6–12 months).

### ***Strengthening the Pharmaceutical Management Information Systems***

**Rationale:** Information required for pharmaceutical management is currently managed in an ad hoc manner, if at all. No person or organization is identified as responsible for tracking or managing this information. Currently, no centralized authority manages the collection and use of this type of data, despite its importance for the appropriate planning and management of pharmaceutical resources.

#### **Issues to consider:**

- **Integration or coordination with the HMIS:** In the process of being set up with support from Johns Hopkins University, the HMIS is not yet fully operational. However, given the scope and volume of information normally collected under by a HMIS, limited opportunity exists to incorporate all the information required for adequate management of the pharmaceutical system in the HMIS.
- **Costs of establishing a PMIS:** Development of an integrated computerized system is likely to be costly and would be a long-term goal. A paper-based system would be cheaper and could be the initial step in development of the system, with computerization to follow at a later date.
- **Location of the PMIS:** The DPM's successor as the primary policy and regulatory authority would be a natural home for the PMIS. Once in place, the PMIS will contribute to the new Medicines Agency's empowerment by giving it the means to monitor and report on the state of the national pharmaceutical system and to facilitate compliance with the applicable laws and regulations.

#### **Key activities (with approximate timelines for implementation):**

- Determine data requirements for the PMIS (6–12 months).
- Develop tools and procedures for collecting and managing data for the PMIS (1–2 years).

- Develop a system for transmitting information, collating it, and using PMIS data at the central level (1–5 years).

### **Strengthening the Pharmacovigilance and Quality Assurance Systems**

**Rationale:** The increased volume of pharmaceuticals coming into the country as a result of increased donor funding as well as through the private sector, and as a result of changes in the national treatment policies, together with the absence of an approved laboratory or pharmacovigilance system, all contribute to the need for a clear pharmacovigilance and quality assurance system.

#### **Issues to consider:**

- **Costs:** What would be the source of the finances required to set up and maintain the pharmacovigilance system and the quality testing laboratory?
- **Location of testing laboratory:** The Kinshasa University laboratory, which is the most frequently mentioned by partners interviewed as the testing laboratory they use, is the likely candidate for the site of a national quality control laboratory. However, its noncentral location and capacity would need to be assessed to ensure these factors do not adversely affect the utility of the site.
- **Location of pharmacovigilance unit:** With the current weakness of the DPM and the absence of an alternate central management authority, the decision of where to best locate the main coordinating unit for a viable pharmacovigilance system will need to be assessed.

#### **Key activities (with approximate timelines for implementation):**

- Develop policies and procedures for a pharmacovigilance system (1–3 years).
- Develop national quality assurance policies and procedures (1–2 years).
- Support the upgrading of at least one laboratory to meet WHO standards (3–5 years).
- Explore the possibility of developing minilabs at ports of entry or other centralized locations (3–5 years).
- Develop the pharmacovigilance network (3–5 years).

## ANNEX 1: ASSUMPTIONS USED IN QUANTIFICATION OF PHARMACEUTICAL REQUIREMENTS FOR USAID-SUPPORTED HEALTH ZONES

### Assumptions for Malaria Pharmaceuticals Quantification Calculations

Assumption	Value	Explanation and Source
Base population	Variable by HZ	Based on census estimates for 2008 (census data for 1984 with estimated annual population growth of 3.1%)
Proportion of the target population in 0–6 years age group	20%	Estimate of the percentage of population in this age group (National Malaria Control Program; NMCP)
Proportion of the target population in 7–13 years age group	25%	Estimate of the percentage of population in this age group (NMCP)
Proportion of the target population in >13 years age group	55%	Estimate of the percentage of population in this age group (NMCP)
Proportion of the target population consisting of pregnant women	4%	Estimate of the percentage of population (NMCP)
Estimated health facility utilization rate	25%	MoH
Proportion of the target population with access to artemisinin-based combination therapies at the health facilities	50%	MoH
Estimated prenatal care utilization rate	85%	Enquête Démographique et de Santé (EDS) 2007
Average number of malaria episodes per year, 0–6 years age group	4	Estimate provided by NMCP
Average number of malaria episodes per year, 7–13 years age group	2	Estimate provided by NMCP
Average number of malaria episodes per year, >13 years age group	1	Estimate provided by NMCP
Percentage of cases of malaria treated with artesunate-amodiaquine (AS-AQ)	100%	
Percentage of cases of malaria treated with quinine	3%	Estimate provided by NMCP
Safety stock	25%	Additional stock to account for lead times and variable consumption patterns
Estimated cost of AS-AQ, 0–6 years package (3 + 3)	\$0.56	IDA (via AXxes)
Estimated cost of AS-AQ, 7–13 years package (6 + 6)	\$0.37	IDA (via AXxes)
Estimated cost of AS-AQ, > 13 years package (12 + 12)	\$0.94	IDA (via AXxes)
Estimated cost of quinine 300 mg	\$0.0362	IDA (via AXxes)
Estimated cost of quinine 600 mg	\$0.0731	IDA (via AXxes)

<b>Assumption</b>	<b>Value</b>	<b>Explanation and Source</b>
Estimated cost of sulfadoxine-pyrimethamine	\$0.0258	IDA (via AXxes)
Estimated cost of insecticide-treated net	\$4.4	AXxes
Transportation cost	25%	For management and transport of medicines (25% of total cost of medicines), from Project AXxes

## **Assumptions for Integrated Management of Childhood Illness Pharmaceuticals Quantification Calculations**

### ***Assumptions for Zinc Quantification Calculations***

<b>Assumption</b>	<b>Value</b>	<b>Source</b>
Base population	Variable by HZ	Based on census data (insert year)
Proportion of the target population in 0–6 months age group	2%	Estimate of the percentage of population in this age group
Proportion of the target population in 7–59 months age group	18%	Estimate of the percentage of population in this age group
Proportion of children under five that are brought for treatment if they have diarrhea	35%	C-DMCI 2006
Average number of diarrhea episodes per year for children under five	3	Estimate provided by the National Diarrheal Disease program
Number of 20-mg zinc tablets needed to treat one episode of diarrhea, 0–6 months age group	5	STGs (1/2 tablet/day for 10 days)
Number of 20-mg zinc tablets needed to treat one episode of diarrhea, 7–59 months age group	10	STGs (1 tablet/day for 10 days)
Safety stock	5%	Additional stock to account for lead times and variable consumption patterns
Cost per 20-mg tablet	\$0.0073	
Number of HZs supported by Project AXxes	57	
Orders already placed by Project AXxes	1,925,000	AXxes
Transportation cost	25%	For management and transport of medicines (25% of total cost of medicines), from Project AXxes

**Assumptions for Oral Rehydration Solution Quantification Calculations**

<b>Assumption</b>	<b>Value</b>	<b>Source</b>
Base population	Variable by HZ	Based on census data (insert year)
Proportion of the target population in 0–6 months age group	2%	Estimate of the percentage of population in this age group
Proportion of the target population in 7–59 months age group	18%	Estimate of the percentage of population in this age group
Proportion of children under five that are brought for treatment if they have diarrhea	35%	C-DMCI 2006
Average number of diarrhea episodes per year for children under five	3	Estimate provided by the National Diarrheal Disease program
Number of oral rehydration solution (ORS) sachets needed to treat one episode of diarrhea, 0–6 months age group	3	STGs
Number of ORS sachets needed to treat one episode of diarrhea, 7–59 months age group	4	STGs
Safety stock	5%	Additional stock to account for lead times and variable consumption patterns
Cost per packet (1 packet/1 liter)	\$0.0089	
Number of HZs supported by Project AXxes	57	
Orders already placed by Project AXxes	200,000	AXxes
Transportation cost	25%	For management and transport of medicines (25% of total cost of medicines)

**Assumptions for Nalidixic Acid Quantification Calculations**

<b>Assumption</b>	<b>Value</b>	<b>Source</b>
Base population	Variable by HZ	Based on census data (insert year)
Proportion of the target population in 6–12 months age group	2%	Estimate of the percentage of population of this age group
Proportion of the target population in 13 months to 3 years age group	8%	Estimate of the percentage of population of this age group
Proportion of the target population in 3 to 5 years age group	8%	Estimate of the percentage of population of this age group
Prevalence of bloody diarrhea in children under five	3%	C-DMCI 2006
Proportion of children under five that are brought for treatment if they have bloody diarrhea	35%	C-DMCI 2006
Average number of bloody diarrhea episodes per year for children under five	1	

<b>Assumption</b>	<b>Value</b>	<b>Source</b>
Number of nalidixic acid tablets (250 mg) needed to treat one episode of bloody diarrhea, 6–12 months age group	5	STGs (1/4 tablet 4 times a day for 5 days)
Number of nalidixic acid tablets (250 mg) needed to treat one episode of bloody diarrhea, 13 months to 3 years age group	10	STGs (1/2 tablet 4 times a day for 5 days)
Number of nalidixic acid tablets (250 mg) needed to treat one episode of bloody diarrhea, 3 to 5 years age group	20	STGs (1 tablet 4 times a day for 5 days)
Safety stock	5%	Additional stock to account for lead times and variable consumption patterns
Cost per tablet	\$0.04	In the MSH <i>Drug Price Indicator Guide</i> 2007, this is the cost for a 500-mg tablet (not 250 mg as the calculations above note)
Orders already placed by Project AXxes	200,000	AXxes
Transportation cost	25%	This cost was not included in the calculations as is

### **Assumptions for Ciprofloxacin Quantification Calculations**

<b>Assumption</b>	<b>Value</b>	<b>Source</b>
Base population	Variable by HZ	Based on census data (insert year)
Proportion of the target population in 0–6 months age group	2%	Estimate of the percentage of population in this age group
Proportion of the target population in 7–12 months age group	2%	Estimate of the percentage of population in this age group
Proportion of the target population in 13 months to 3 years age group	8%	Estimate of the percentage of population of this age group
Proportion of the target population in 3 to 5 years age group	8%	Estimation of the percentage of population in this age group
Prevalence of bloody diarrhea in children under five	3%	C-DMCI 2006
Proportion of children under five that are brought for treatment if they have bloody diarrhea	35%	C-DMCI 2006
Average number of bloody diarrhea episodes per year for children under five	1	
Expected failure rate of the first-line treatment for bloody diarrhea (nalidixic acid)	20%	
Number of ciprofloxacin tablets (250 mg) needed to treat one episode of bloody diarrhea, 0–6 months age group	5	STGs (specific dosing?)
Number of ciprofloxacin tablets (250 mg) needed to treat one episode of bloody	8	STGs (specific dosing?)

*Annex I: Assumptions Used in Quantification of Pharmaceutical Requirements for USAID-Supported Health Zones*

<b>Assumption</b>	<b>Value</b>	<b>Source</b>
diarrhea, 7–12 months age group		
Number of ciprofloxacin tablets (250 mg) needed to treat one episode of bloody diarrhea, 13 months to 3 years age group	10	STGs (specific dosing?)
Number of ciprofloxacin tablets (250 mg) needed to treat one episode of bloody diarrhea, 3 to 5 years age group	15	STGs (specific dosing?)
Safety stock	5%	Additional stock to account for lead times and variable consumption patterns
Cost per tablet	\$0.0045	
Orders already placed by the AXxes project	73,700	AXxes
Transportation cost	25%	For management and transport of medicines (25% of total cost of medicines), from AXxes

**Assumptions for TB Quantification Calculations**

<b>Assumption</b>	<b>Value</b>	<b>Explanation and Source</b>
Base population	Variable by HZ	Based on census estimates for 2008 (census data for 1984 with estimated annual population growth of 3.1%)
Proportion of the target population in < 6 years age group	24%	Estimate of the percentage of population in this age group
Proportion of the target population in 6–12 years age group	21%	Estimate of the percentage of population in this age group
Proportion of the target population in > 12 years (adult) age group	55%	Estimate of the percentage of population in this age group
Estimated annual incidence of TB	0.3%	300 cases/100,000 population (PNT)
Estimated proportion of TB cases detected and treated	70%	Estimate provided by PNT
Proportion of TB cases detected that are classified as Category 1	75%	Estimate provided by PNT
Proportion of TB cases detected that are classified as Category 2	7%	Estimate provided by PNT
Proportion of TB cases detected that are classified as Category 3	18%	Estimate provided by PNT
Category 1 treatment regimen	2RHZE/4RH	2 months on rifampicin, isoniazid, pyrazinamide and ethambutol; then 4 months on rifampicin and isoniazid
Category 2 treatment regimen	2SRHZE/ 1RHZE/ 5RHE	2 months on streptomycin injection, rifampicin, isoniazid, pyrazinamide, and ethambutol; then 1 month on rifampicin and isoniazid; then 5 months on rifampicin, isoniazid, and ethambutol

Assumption	Value	Explanation and Source
Category 3 treatment regimen	2RHZ/4RH	2 months on rifampicin, isoniazid, and pyrazinamide; then 4 months on rifampicin and isoniazid
Estimated cost of RHZE	\$0.1249	Estimate provided by PNT
Estimated cost of RH (adult)	\$0.0294	Estimate provided by PNT
Estimated cost of RH (child)	\$0.0220	Estimate provided by PNT
Estimated cost of RHZ (child)	\$0.0271	Estimate provided by PNT
Estimated cost of RHE	\$0.0401	Estimate provided by PNT
Estimated cost of ethambutol	\$0.0586	Estimate provided by PNT
Estimated cost of streptomycin 1 g injection	\$1.49	Estimate provided by PNT
Estimated cost of syringe	\$0.3448	Estimate provided by PNT
Estimated cost of water for injection	\$0.1724	Estimate provided by PNT

### Assumptions for Maternal Health Quantification Calculations

Assumption	Value	Explanation and Source
Base population	Variable by HZ	Based on census estimates for 2008 (census data for 1984 with estimated annual population growth of 3.1%)
Proportion of the target population consisting of pregnant women	4%	Estimate of the percentage of population (NMCP)
Estimated prenatal care utilization rate	85%	EDS 2007
Number of mebendazole 100 mg given to each pregnant woman	6	2 tablets once a day for 3 days during the third trimester
Estimated cost of mebendazole 100 mg	\$0.0046	MSH <i>Drug Price Indicator Guide 2007</i>
Number of iron sulfate 200 mg + folic acid 0.25 mg given to each pregnant woman	180	1 tablet once a day for 6 months, 3 months prenatal and 3 months postnatal
Estimated cost of iron sulfate 200 mg + folic acid 0.25 mg	\$0.0039	MSH <i>Drug Price Indicator Guide 2007</i>
Estimated proportion of deliveries assisted by a skilled birth attendant	78%	EDS – RDC 2007
Estimated proportion of deliveries assisted by a skilled birth attendant where active management of third stage of labor is practiced	67%	Report from Project AXxes
Number of oxytocin 10 IU injection ampoules per delivery	1	
Estimated cost of oxytocin 10 IU injection	\$0.0644	MSH <i>Drug Price Indicator Guide 2007</i>
Estimated proportion of deliveries assisted by a skilled birth attendant where butylscopolamine is used	50%	
Number of butylscopolamine 20 mg injection ampoules per delivery	2	

*Annex I: Assumptions Used in Quantification of Pharmaceutical Requirements for USAID-Supported Health Zones*

Assumption	Value	Explanation and Source
Estimated cost of butylscopolamine 20 mg injection	\$0.12	MSH <i>Drug Price Indicator Guide</i> 2007
Reserve requirements	25%	From Project AXxes

### Assumptions for ARV Quantification Calculations

Assumption	Adults	Children
Total population		13,495,617
Number eligible for treatment	91,095	22,774
Estimated number who will receive treatment at the beginning of the program	500	350
Targeted number to receive treatment in year 1 of program	9,110	2,277
Estimated number of new infections	8,610	1,927
Estimated monthly increase in patients receiving treatment	717	161
Patients receiving first-line treatment	90%	97%
Patients receiving second-line treatment	10%	3%
Procurement period		12 months
Security stock		3 months

### Assumptions for Prevention of Mother-to-Child Transmission Quantification Calculations

Assumption	A1	A2
Estimated number of HIV-positive women expected to receive treatment in targeted health zones	1200	1500
Estimated number of newborns expected to receive treatment in targeted health zones	1,140	1425
Number of sites anticipated to offer prevention of mother-to-child transmission (PMTCT) in targeted health zones	129	135
Number of sites currently offering PMTCT in targeted health zones	93	
Estimated number of ARV 300 mg tablets required for PMTCT by each woman		183
Estimated number of NVP 200 mg tablets required for PMTCT by each woman		1
Estimated number of 3TC 150 mg tablets required for PMTCT by each woman		16
Estimated number of flacons of ARV 10 mg/ml required for PMTCT by each newborn (dose 4 mg/kg twice a day for seven days)		16.8
Estimated number of flacons of NVP 10 mg/ml required for PMTCT by each newborn (dose 2 mg/kg stat dose)		0.6
Estimated price AZT 300 mg (MSH <i>Drug Price Indicator Guide</i> 2007)		\$0.15

<b>Assumption</b>	<b>A1</b>	<b>A2</b>
Estimated price NVP 200 mg (MSH <i>Drug Price Indicator Guide</i> 2007)		\$0.07
Estimated price AZT 10 mg/ml (100 ml flacon) (MSH <i>Drug Price Indicator Guide</i> 2007)		\$0.068
Estimated price NVP 10 mg/ml (100 ml flacon) (MSH <i>Drug Price Indicator Guide</i> 2007)		\$0.013

### **Assumptions for Family Planning Products Quantification Calculations**

<b>Assumption</b>	<b>Value</b>	<b>Explanation and Source</b>
Base population	Variable by HZ	Based on census estimates for 2008 (census data for 1984 with estimated annual population growth of 3.1%)
Proportion of women of reproductive age	22%	EDS 2007
Proportion of women of reproductive age who use male condoms	4.8%	EDS 2007
Average number of male condoms per woman per year (CYP)	120	Plan national de securisation des produits de Santé Reproductive, PNSR-RDC 2005
Proportion of women of reproductive age who use female condoms	1%	Plan national de securisation des produits de Santé Reproductive, PNSR-RDC 2005
Average number of female condoms per woman per year (CYP)	150	Plan national de securisation des produits de Santé Reproductive, PNSR
Proportion of women of reproductive age who use cycle beads	1%	Plan national de securisation des produits de Santé Reproductive, PNSR
Average number of cycle beads per woman per year (CYP)	2	Plan national de securisation des produits de Santé Reproductive, PNSR-RDC 2005
Proportion of women of reproductive age who use Microgynon30	0.4%	EDS 2007
Average number of Microgynon30 plaquettes per woman per year (CYP)	12	Plan national de securisation des produits de Santé Reproductive, PNSR-RDC 2005
Proportion of women of reproductive age who use Norgestrel (Ovrette)	0.2%	EDS 2007
Average number of Norgestrel (Ovrette) plaquettes per woman per year (CYP)	12	Plan national de securisation des produits de Santé Reproductive, PNSR-RDC 2005
Proportion of women of reproductive age who use Lofemenal	0.2%	EDS 2007
Average number of Lofemenal plaquettes per woman per year (CYP)	12	Plan national de securisation des produits de Santé Reproductive, PNSR-RDC 2005
Proportion of women of reproductive age who use Levonogesteral	0.2%	EDS 2007
Average number of Levonogesteral plaquettes per woman per year (CYP)	12	Plan national de securisation des produits de Santé Reproductive, PNSR-RDC 2005
Proportion of women of reproductive age who use injectable contraceptives	0.3%	EDS 2007
Proportion of women using injectable contraceptives who use Norethisterone	30%	EDS 2007

*Annex 1: Assumptions Used in Quantification of Pharmaceutical Requirements for USAID-Supported Health Zones*

<b>Assumption</b>	<b>Value</b>	<b>Explanation and Source</b>
Average number of ampoules of Norethisterone per woman per year	6	
Proportion of women using injectable contraceptives who use Depo-provera	70%	EDS 2007
Average number of ampoules of Depo-Provera per woman per year	4	
Proportion of women of reproductive age who use an intra-uterine device (IUD)	0.1%	EDS 2007
Average number of IUDs per woman per 3.5 years (CYP)	3.5	
Reserve requirements	25%	From Project AXxes

**Assumptions for Nutrition Products Quantification Calculations**

<b>Assumption</b>	<b>Value</b>	<b>Explanation and Source</b>
Base population	Variable by HZ	Based on census estimates for 2008 (census data for 1984 with estimated annual population growth of 3.1%)
Proportion of children 0–59 months	20%	
Prevalence of severe malnutrition of children 0–59 months	8%	EDS 2007
Number of mebendazole tablets per child with severe malnutrition	6	
Number of iron + folic acid tablets per child with severe malnutrition	14	
Prevalence of anemia in children under 5 years	71%	
Rate of health facility utilization for the management of anemia	50%	
Number of iron + folic acid tablets per child with anemia	7	
Estimated cost of mebendazole	\$0.0046	
Estimated cost of iron + folic acid	\$0.0038	



## ANNEX 2: QUANTIFICATION OF PHARMACEUTICAL REQUIREMENTS FOR PROCUREMENT, 2009–2010

Formulation	Patient description/ symptom for treatment	Estimated population 2009	Estimated population 2010	Estimated requirements 2009	Estimated requirements 2010	Estimated CIF cost 2009 (USD)	Estimated CIF cost 2010 (USD)
<b>MALARIA</b>							
<b>ACT</b>							
AS+AQ 3+3	Children 0–6 years coming to consultation	674,781	695,699	3,373,904	3,478,495	2,361,732.98	2,434,946.70
AS+AQ 6+6	Children 7–13 years coming to consultation	843,476	869,624	2,108,690	2,174,060	975,269.20	1,005,502.54
AS+AQ 12+12	> 13 years coming to consultation	1,855,647	1,913,172	2,319,559	2,391,466	2,725,482.03	2,809,971.97
<b>QUININE</b>							
Quinine 300 mg	Children 0–6 years coming to consultation	674,781	695,699	108,520	111,884	4,910.54	5,062.76
Quinine 300 mg	Children 7–13 years coming to consultation	843,476	869,624	1,328,475	1,369,658	60,113.48	61,977.00
Quinine 500 mg	> 13 years coming to consultation	1,855,647	1,913,172	1,461,322	1,506,623	133,528.32	137,667.70
Injectable quinine	People coming for consultation	3,373,904	3,478,495	1,287,237	1,327,142	163,961.85	169,044.67
Glucose (solution)	People coming for consultation	3,373,904	3,478,495	263,908	272,089	296,896.32	306,100.11
SP 500/25	coming for prenatal care	458,851	473,075	3,441,382	3,548,065	110,984.58	114,425.10
Insecticide- treated net							
Pregnant women	coming for prenatal care	458,851	473,075	481,794	496,729	2,649,864.40	2,732,010.19

Formulation	Patient description/ symptom for treatment	Estimated population 2009	Estimated population 2010	Estimated requirements 2009	Estimated requirements 2010	Estimated CIF cost 2009 (USD)	Estimated CIF cost 2010 (USD)
Children < 5 years	coming for preschool consultation	1,657,937	1,709,333	1,740,833	1,794,799	9,574,584.00	9,871,396.10
Microscopes	Number required 1st year/each year thereafter	77	77	77	23	96,750.00	96,750.00
Reagent	Children 7-13 years	421,738	434,812	354	365		
	> 13 years	927,824	956,587	390	402	92,998.18	95,881.12
<b>MALARIA TOTAL</b>			—			\$19,247,075.87	\$19,840,735.98

**IMCI**

Amoxicillin	children accessing pneumonia treatment						
	< 6 months	107,965	111,312	516,936	532,961	12,277.23	12,657.83
	6–12 months	107,965	111,312	969,255	999,302	23,019.81	23,733.43
	12 months– 3 years	431,860	445,247	7,754,042	7,994,417	184,158.49	189,867.40
	3–5 years	431,860	445,247	15,430,169	15,908,505	366,466.52	377,826.98
Co- trimoxazole	children accessing pneumonia treatment						
	< 6 months	107,965	111,312	1,700,448	1,753,162	23,381.16	24,105.97
	6–12 months	107,965	111,312	3,400,895	3,506,323	46,762.31	48,211.94

*Annex 2: Quantification of Pharmaceutical Requirements for Procurement, 2009–2010*

Formulation	Patient description/ symptom for treatment	Estimated population 2009	Estimated population 2010	Estimated requirements 2009	Estimated requirements 2010	Estimated CIF cost 2009 (USD)	Estimated CIF cost 2010 (USD)
	12 months– 3 years	431,860	445,247	20,405,373	21,037,939	280,573.88	289,271.67
	3–5 years	431,860	445,247	27,207,164	28,050,586	374,098.50	385,695.56
Zinc			-		-		
	0–6 months	94,469	97,398	1,487,892	1,534,016	59,143.70	60,977.15
	7–59 months	850,224	876,581	26,782,052	27,612,296	1,064,586.56	1,097,588.75
ORS			-				
	0–6 months	94,469	97,398	892,735	920,410	80,122.97	82,606.78
	7–59 months	850,224	876,581	10,712,821	11,044,918	961,475.66	991,281.41
			-				
Ciprofloxacin	children < 5 years with bloody discharge not responding to nalidixic acid	28,341	29,219	66,955	69,031	376.62	388.30
Nalidixic acid	children < 5 years with bloody discharge	25,507	26,297	371,973	383,504	18,598.65	19,175.21
<b>IMCI TOTAL</b>						<b>\$3,275,586.54</b>	<b>\$3,377,129.72</b>
<b>TB</b>							
Preparation water	Cat 2 detected cases	1,984	2,045	178,547	184,082	38,476.88	39,669.66
Syringes	Cat 2 detected cases	1,984	2,045	357,094	368,164	153,907.53	158,678.66

Formulation	Patient description/ symptom for treatment	Estimated population 2009	Estimated population 2010	Estimated requirements 2009	Estimated requirements 2010	Estimated CIF cost 2009 (USD)	Estimated CIF cost 2010 (USD)
Streptomycin	Cat 2 detected cases	1,984	2,045	178,547	184,082	332,543.81	342,852.67
RHE	Cat 2 detected cases	1,984	2,045	1,541,456	1,589,241	77,265.48	79,660.71
Ethambutol	Cat 1 children 6-12	4,464	4,602	328,080	338,251	24,031.87	24,776.86
RHZ child	Cat 1+3 children <12	11,861	12,228	4,020,751	4,145,394	136,202.95	140,425.24
RH child	Cat 1+3 children <12	11,861	12,228	8,041,502	8,290,789	221,141.32	227,996.70
RH adult	Cat 1+3 adults	14,496	14,946	8,741,279	9,012,259	321,242.01	331,200.51
RHZE	cat 2 + cat 1 adult	13,674	14,098	4,450,178	4,588,134	694,784.04	716,322.35
<b>TB TOTAL</b>						<b>\$1,999,595.88</b>	<b>\$2,061,583.35</b>

**RH/FP**

Mebendazole	pregnant women accessing prenatal care	458,851	473,075	3,441,382	3,548,065	19,787.95	20,401.37
Iron sulfate + folic acid	pregnant women accessing prenatal clinics	458,851	473,075	103,241,470	106,441,956	503,302.17	518,904.53
Oxytocin	pro. attendant-assisted deliveries (AMTSL)	282,112	290,858	352,640	363,572	28,387.56	29,267.57
Butyl-scopolamine	pro. attendant-assisted deliveries requiring BSA	281,715	290,448	704,288	726,121	105,643.16	108,918.10

*Annex 2: Quantification of Pharmaceutical Requirements for Procurement, 2009–2010*

<b>Formulation</b>	<b>Patient description/ symptom for treatment</b>	<b>Estimated population 2009</b>	<b>Estimated population 2010</b>	<b>Estimated requirements 2009</b>	<b>Estimated requirements 2010</b>	<b>Estimated CIF cost 2009 (USD)</b>	<b>Estimated CIF cost 2010 (USD)</b>
Syringes	pro. attendant-assisted deliveries requiring AMTSL and BSA	563,827	581,306	1,056,928	1,089,693	33,029.01	34,052.91
Female condoms	Reproductive age women using female condoms	29,690	30,611	5,566,942	5,739,517	5,652,185.81	5,827,403.57
Male condoms		142,514	146,932	21,377,057	22,039,746	521,065.77	537,218.81
Cycle beads	Reproductive age women using cycle beads	29,690	30,611	74,226	76,527	74,225.89	76,526.90
Microgynon 30	Reproductive age women using Microgynon	11,876	12,244	178,142	183,665	74,418.88	76,725.87
Ovrette	Reproductive age women using Ovrette	5,938	6,122	89,071	91,832	20,040.99	20,662.26
Lofemenal	Reproductive age women using Lofem	5,938	6,122	89,071	91,832	21,154.38	21,810.17
Norethisterone	Reproductive age women using Noristerat among those using injectables	2,672	2,755	20,041	20,662	31,559.55	32,537.90
Depo Provera	Reproductive age women using Depo among those using injectables	6,235	6,428	31,175	32,141	16,931.85	17,456.74

Formulation	Patient description/ symptom for treatment	Estimated population 2009	Estimated population 2010	Estimated requirements 2009	Estimated requirements 2010	Estimated CIF cost 2009 (USD)	Estimated CIF cost 2010 (USD)
Syringes	Reproductive age women using injectables	8,907	9,183	51,216	52,804	22,074.04	22,758.33
Levonorgestrel	Reproductive age women requiring levonorgestrel	5,938	6,122	14,845	15,305	3,766.96	3,883.74
IUDs	2009: sexually active women using IUD; 2010 additional sexually active women using IUD	2,969	3,061	2,969	92	4,383.97	4,519.87
<b>RH/FP TOTAL</b>						<b>\$7,131,957.94</b>	<b>\$7,353,048.64</b>
<b>NUTRITION</b>							
Iron sulfate/folic acid	anemic children reporting for treatment	958,189	987,893	11,676,408	12,038,376	55,462.94	57,182.29
Mebendazole	children <5 years with acute severe malnutrition	215,930	222,624	1,554,695	1,602,891	8,939.50	9,216.62
<b>NUTRITION TOTAL</b>						<b>\$64,402.43</b>	<b>\$66,398.91</b>
<b>WATER SANITATION</b>							
Pur® water supplement	Number of average size households	1,927,945	1,987,712	9,851,800	10,157,206	\$2,462,950.10	\$2,539,301.56

*Annex 2: Quantification of Pharmaceutical Requirements for Procurement, 2009–2010*

Formulation	Patient description/ symptom for treatment	Estimated population 2009	Estimated population 2010	Estimated requirements 2009	Estimated requirements 2010	Estimated CIF cost 2009 (USD)	Estimated CIF cost 2010 (USD)
<b>HIV/AIDS</b>							
	Targeted number of adult patients, old and new, pills, 1st and 2nd line	9,110	17,726				
D4T 30+3TC 150+NVP 200				40,500	74,755	8,529.30	15,743.33
AZT 300+3TC 150 (adults)				460,800	850,542	43,130.88	79,610.74
AZT 300+3TC 150 (children)				229,050	422,779	128,634.48	237,432.80
EFV 600				45,000	83,061	31,063.50	57,336.83
ABC 300				15,750	29,071	9,766.58	18,027.09
DDI 250				6,750	12,459	5,449.28	10,058.24
DDI 400				90,000	166,121	35,802.00	66,083.13
	Targeted number of children, old and new patients, 1st and 2nd line	2,140	3,950				
3TC 10 mg/ml				43,248,600	79,828,023	540,607.50	997,850.29
D4T 1 mg/ml							
AZT 10 mg/ml				86,497,200	159,656,047	7,352,262.00	13,570,763.97
NVP 10 mg/ml				2,843,100	5,247,778	46,200.38	85,276.39
EFV 30 mg/ml							

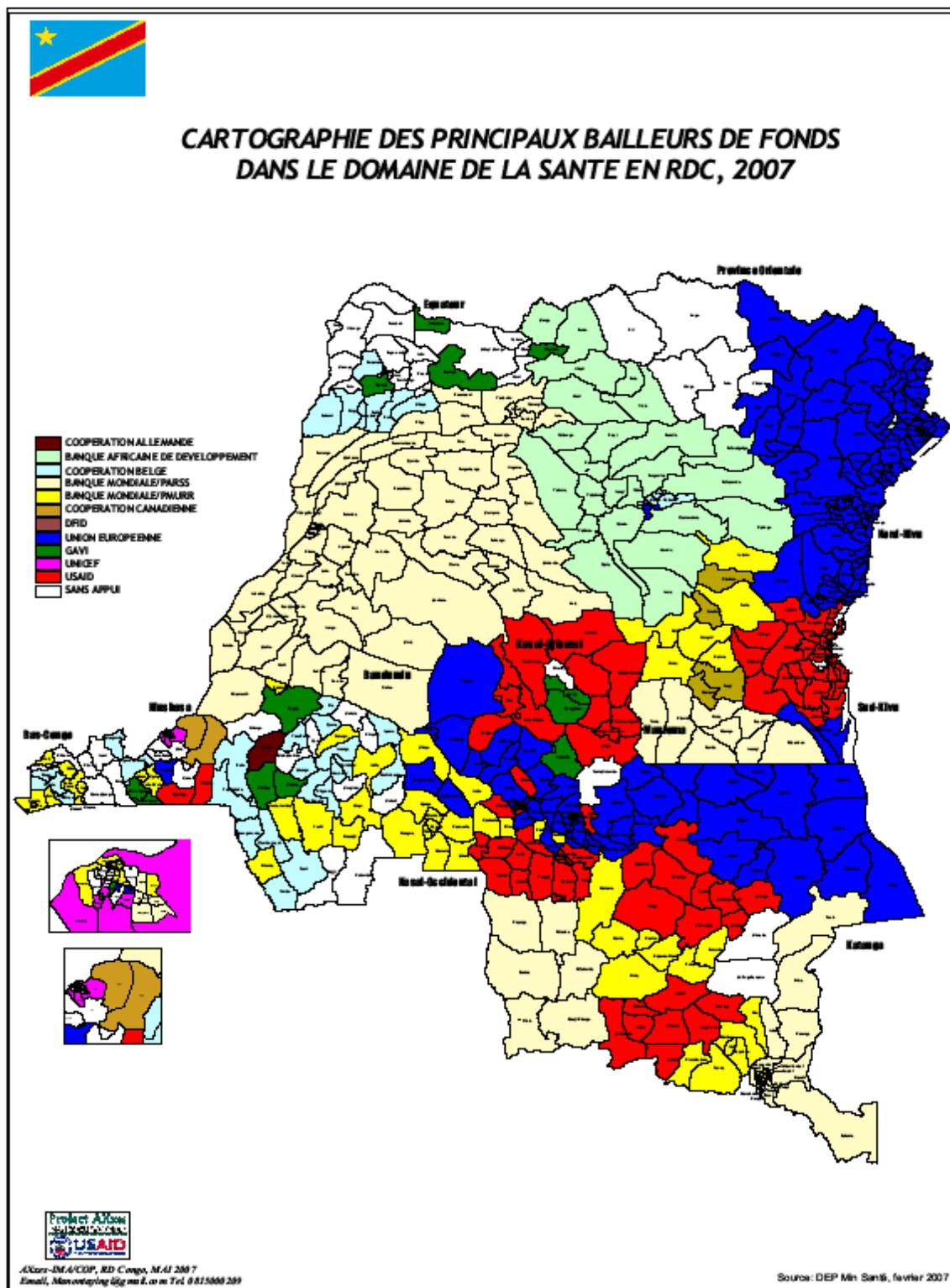
Formulation	Patient description/ symptom for treatment	Estimated population 2009	Estimated population 2010	Estimated requirements 2009	Estimated requirements 2010	Estimated CIF cost 2009 (USD)	Estimated CIF cost 2010 (USD)
LPV/R 80 mg/20 mg/ml				18,119,088	33,444,110	32,161,380.35	59,363,295.51
ABC 20 mg/ml				1,337,611	2,468,954	123,728.99	228,378.27
DDI 10 mg/ml				1,672,013	3,086,193	56,430.45	104,159.01
	Targeted number of children, old and new patients, pills, 1st and 2nd line	138	255				
AZT 300+3TC 150+NVP 200				8,883,896	16,397,845	1,998,876.61	3,689,515.23
AZT 300+3TC 150				1,158,085	2,137,586	260,569.04	480,956.87
D4T 30+3TC 150							
NVP 200				46,058	85,013	3,742.17	6,907.28
EFV 200							
ABC 300				308,679	569,759	227,651.05	420,197.03
DDI 250				154,340	284,879	102,250.05	188,732.56
PMTCT							
AZT 300 mg	sero+ mothers	1,200	1,500	274,500	343,125	51,468.75	64,335.94
NVP 200 mg	sero+ mothers	1,200	1,500	1,500	1,875	121.88	152.34
AZT 10 mg/ml	babies born from sero+ mothers	1,140	1,425	178,125	214,125	15,140.63	18,200.63

*Annex 2: Quantification of Pharmaceutical Requirements for Procurement, 2009–2010*

Formulation	Patient description/ symptom for treatment	Estimated population 2009	Estimated population 2010	Estimated requirements 2009	Estimated requirements 2010	Estimated CIF cost 2009 (USD)	Estimated CIF cost 2010 (USD)
NVP 10 mg/ml	babies born from sero+ mothers	1,140	1,425	178,125	214,125	2,894.53	3,479.53
<b>HIV/AIDS TOTAL</b>						\$43,205,700.37	\$79,706,493.04
<b>COMMODI- TIES TOTAL</b>						\$77,387,269.15	\$114,944,691.19
Notes:							
1- Estimated requirements include safety stock							
2- Estimated requirements do not take account of outstanding/pending orders							
3- CIF cost = Cost of goods + associated Insurance and freight cost up to the port of entry into the DRC							



### ANNEX 3: MAP OF PRINCIPAL DONORS





## ANNEX 4: FEDECAME ESSENTIAL MEDICINES LIST

*NB: The highlighted products are also included in the AXxes EML.*

Acetyl Salicylate de Lysine, 1g, Vial, Unité
Acide Acetylsalicylique, 500mg, Tab, 1000, Vrac
Acide Folique, 5mg, Tab, 1000, Vrac
Aluminium Hydroxyde, 500mg, Tab, 1000, Vrac
Aminophylline, 25mg/ml, 10ml, Amp, Unité
Amoxicilline, 125mg/ml, 100ml, flacon, Unité
Amoxicilline, 250mg, Caps, 1000, Vrac
Amoxicilline, 500mg, Caps, 1000, Vrac
Ampicilline, 1g, Vial, Unité.
Atropine, 1mg/ml, 1ml, Amp, Unité
Butylhyoscine bromure (Butylscopolamine), 10mg, Tab, 1000, Vrac
Butylhyoscine bromure (Butylscopolamine), 20mg/ml, 1ml, Amp, Unité
Calcium gluconate, 100mg/ml, 10ml, Amp, Unité
Catheter court IV avec site d'injection, u.u., 18G, Unité
Catheter court IV avec site d'injection, u.u., 22G, Unité
Ceftriaxone, 1g, Vial, Unité
Chloramphenicol sodium succinate, 1g, Vial, Unité
Chloramphenicol, 250mg, Caps, 1000, Vrac
Chlorhexidine + Cetrimide, 1,5%+15%, 1 litre, flacon, Unité
Chlorpromazine chlorhydrate, 25mg/ml, 2ml, Amp, Unité
Chlorure de sodium, 0,9%, 500ml, Perfusion, Unité
Cimétidine, 200mg, Tab, 1000, Vrac
Ciprofloxacin Chlorhydrate, 500mg, Tab, 100, Vrac
Ciprofloxacin, 2mg/ml, 100ml, Flacon, Unité
Coton hydrophile, rouleau, 500g, Unité
Cotrimoxazole, 240mg/5ml, 100ml, flacon, Unité
Cotrimoxazole, 480mg, Tab, 1000, Vrac
Dexamethasone sodium phosphate, 4mg/ml, 1ml, Amp, Unité
Dextrose (Glucose) + NaCl, 5%+0,9%, 500ml, Perfusion, Unité
Dextrose (Glucose), 5%, 500ml, Perfusion, Unité
Dextrose (Glucose), 50%, 50ml, Vial, Unité
Diazepam, 5mg, Tab, 1000, Vrac

Diazepam, 5mg/ml, 2ml, Amp, Unité
Diclofenac sodique, 25mg/ml, 3ml, Amp, Unité
Diclofenac, 25mg, Tab, 1000, Vrac
Digoxine, 250mcg, Tab, 1000, Vrac
Doxycycline, 100mg, Tab, 1000, Vrac
Eau pour injection, 10ml, Vial, Unité
Epinéphrine (Adrenaline), 1mg/ml, 1ml, Amp, Unité
Erythromycine, 250mg, Tab, 1000, Vrac
Erythromycine, 250mg/5ml, 100ml, flacon, Unité
Fer sulfate+Acide Folique, 200mg+0,25mg, Tab, 1000, Vrac
Furosemide, 10mg/ml, 2ml, Amp, Unité
Gants chirurgicaux latex steriles, u.u., Taille 7.5, Unité
Gants chirurgicaux latex stériles, u.u., Taille 8, Unité
Gants d'examen latex non stériles, u.u., Medium, 100
Gaze, rouleau, 90cmx91m, Unité
Gentamicine, 40mg/ml, 2ml, Amp, Unité
Griseofulvine, 125mg, Tab, 1000, Vrac
Hydrocortisone sodium succinate, 100mg, Vial, Unité
Ibuprofen, 200mg, Tab, 1000, Vrac
Ketamine, 50mg/ml, 10ml, Vial, Unité
Levamisole, 50mg, Tab, 1000, Vrac
Lidocaïne chlorhydrate, 2%, 20 ml, Vial, Unité
Lidocaïne chlorhydrate+dextrose, 5%+7,5%/2 ml, Amp, Unité
Mebendazole, 100mg, Tab, 1000, Vrac
Methylergometrine maleate, 0,2mg/ml, 1ml, Amp, Unité
Métoclopramide chlorhydrate, 5mg/ml, 2ml, Amp, Unité
Metronidazole, 250mg, Tab, 1000, Vrac
Métronidazole, 5mg/ml, 100ml, Flacon, Unité
Multivitamines, Tab, 1000, Vrac
Nystatin, 100.000 IU, Tab vaginal, 100, Vrac
Oxytocine, 10 UI/ml, 1ml, Amp, Unité
Papaverine Chlorhydrate, 40mg, Tab, 1000, Vrac
Paracetamol, 500mg, Tab, 1000, Vrac
Penicilline Benzathine, 2,4MUI, Vial, Unité
Penicilline Benzyl (Peni G cristal. Peni), 1MUI, Vial, Unité

*Annex 4: FEDECAME Essential Medicines List*

Penicilline Benzyl (Peni G cristal. Peni), 5MUI, Vial, Unité
Penicilline Procaine+Benzyl, 3+1MUI, Vial, Unité
Phenobarbital, 50mg, Tab, 1000, Vrac
Phenoxymethylpenicillin (Peni V) , 250mg, Tab, 1000, Vrac
Polyvidone iodée, 10%, 200ml, flacon, Unité
Prednisolone, 5mg, Tab, 1000, Vrac
Promethazine chlorhydrate, 25mg/ml, 2ml, Amp, Unité
Promethazine, 25 mg, Tab, 1000, Vrac
Quinine bichlorhydrate, 20% en base, 15ml, flacon, Unité
Quinine bichlorhydrate, 500mg/2ml, 2ml, Amp, Unité
Quinine HCl/Sulf, 250mg base, Tab, 1000, Vrac
Quinine HCl/Sulf, 500mg base, Tab, 1000, Vrac
Ringer lactate (Solution de Hartmann), 500ml, Perfusion, Unité
Sachet plastique pour médicament, 10x8cm, Sachet, 500
Sachet plastique pour médicament, 6x8cm, Sachet, 500
Salbutamol sulfate, 4mg, Tab, 1000, Vrac
Sel de Réhydratation Orale, pour 1l, sachet, Unité
Seringue Luer, 10ml + aiguille 21G, u.u., Unité
Seringue Luer, 2ml + aiguille 21G, u.u., Unité
Seringue Luer, 5ml + aiguille 21G, u.u., Unité
Serum antitétanique 1.500 UI/ml, 1ml, Amp, Unité
Set de perfusion
Sparadrap, rouleau, 2,5cmx5m, Unité
Sparadrap, rouleau, 5cmx5 m, Unité
Sulfadoxine+pyrimethamine, 500mg+25mg, Tab, 1000, Vrac
Tetracycline, 1%, pommade, tube, 5g, Unité
Thiamine (Vitamine B1), 50mg/ml, 2ml, Amp, Unité
Thiamine, 50mg, Tab, 1000, Vrac



## ANNEX 5: PROJECT AXES ESSENTIAL MEDICINES LIST

*NB: The highlighted products are also included in the FEDECAME EML.*

Description	Unit
Acetylsalicylic acid 500mg	1000 TAB
Aciclovir 200mg dispersible	500 TAB
Adhesive tape 2.50cm x 5m	8 ROL
Aluminium hydroxide 500mg	1000 TAB
Aminophylline 100mg	1000 TAB
Aminophylline 250mg/10ml inj	100 AMP
Amoxicillin 125mg/5ml powder for susp 100ml	40 BTL
Amoxicillin 250mg cap	1000 CAP
Ampicillin 1 gram powder for inj	50 VLS
Artesunate 50mg + amodiaquine 153mg co-blister	12+12TABBL
Artesunate 50mg + amodiaquine 153mg co-blister	6+6 TAB BL
Artesunate 50mg + amodiaquine 153mg co-blister	3+3 TAB BL
Atropine sulphate 1mg/ml, 1ml inj	100 AMP
Benzathine penicillin 2.4 MIU powder for inj	50 VLS
Benzylbenzoate 25% application	1 L
Benzylpenicillin 5 MIU powder for inj	50 VLS
Cefixime 200 mg	100 TAB BL
Ceftriaxone 250mg powder for injection	10 VLS
Cetrimide 15%+chlorhexidine gluconate 1.5%	5l
Chloramphenicol 250mg	1000 CAP
Chlorphenamine maleate 4mg	1000 TAB
Ciprofloxacin 500mg	100 TAB
Cloxacillin 500mg	1000 CAP
Co-trimoxazole 400mg+80mg	1000 TAB
Cotton wool absorbent BP/EurP. 500g	ROL
Dextrose 5% 500ml btl with nipple (no set)	20 BTL
Diazepam 10mg/2ml inj (pt)	100 AMP
Diazepam 5mg (pt)	1000 TAB
Digoxin 0.25mg	1000 TAB
Doxycycline 100mg (as hyclate)	1000 TAB
Epinephrine (adrenaline) 1mg/ml, 1ml inj.	100 AMP

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Description	Unit
Erythromycin 125mg/5ml pwd for susp 100ml	250 BTL
Erythromycin 250mg (as stearate)	1000 TAB
Ferrous sulphate 200mg + Folic acid 0.25mg	1000 TAB
Ferrous sulphate 200mg + Folic acid 0.25mg	100 TAB BL
Folic acid 5mg	1000 TAB
Furosemide 20mg/2ml inj	100 AMP
Furosemide 40mg	1000 TAB
Gentamicin 80mg/2ml inj	100 AMP
Glibenclamide 5mg	1000 TAB
Hydrochlorothiazide 25mg	1000 TAB
Hydrocortisone 100mg (as sodium succinate) inj	50 VLS
Hyoscine butylbromide 20mg/ml, 1ml inj	100 AMP
Hyoscine butylbromide 10mg	1000 TAB
Indometacin 25mg	1000 CAP
Insulin isophane 100 IU/ml inj. nph 10ml HM **	10 VLS
Ketamine 50mg/ml, 10ml inj	5 VLS
Lidocaine HCl 5%+dextrose 7.5% 2ml spinal inj	100 AMP
Mebendazole 100mg	1000TAB
Methylergometrine maleate 0.2mg/ml, 1ml inj *	100 AMP
Metronidazole 250mg	1000 TAB
Miconazole 10mg muco-adhesive buccal tab	350 TAB BL
Miconazole 2% cream 30 gram	50 TUB
Multivitamin coated	1000 TAB
Nalidixic acid 500mg	1000 TAB
Needle Luer 21G x 1-1/2" (0.8x38mm) disp.	100 PCE
Needle Luer 23G x 1" (0.6x25mm) disp.	100 PCE
Nystatin 100,000 IU vaginal	100 TAB
Nystatin 500,000 IU oral coated	100 TAB
Oral Rehydration Salt 20.5g/liter (low osm)	100 SAC
Oxytocin 10 IU/ml, 1ml inj *	100 AMP
Paracetamol 100mg	1000 TAB
Paracetamol 500mg	1000 TAB
Pentazocine 30mg/ml, 1ml inj (pt)	100 AMP
Phenobarbital 30mg (pt)	1000 TAB

*Annex 5: Project AXxes Essential Medicines List*

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<b>Description</b>	<b>Unit</b>
Phenobarbital sodium 200mg/2ml inj (pt)	100 AMP
Phenoxymethylpenicillin 250mg	1000 TAB
Phenytoin acid equiv. to 100mg Phenytoin sodium	1000 TAB
Prednisolone 5mg	1000 TAB
Procaine pen.3 MIU+benzylpen 1 MIU (PPF) powd.inj.	50 VLS
Quinine di-HCl 600mg/2ml inj	10 X 10AMP
Quinine sulphate 300mg film coated	1000 TAB
Salbutamol 4mg	1000 TAB
Scalp vein infusion set 21G	100 PCE
Scalp vein infusion set 23G	100 PCE
Sodium chloride 0.9%, 500ml with nipple (no set)	20 BTL
Sulfadoxine 500mg+pyrimethamine 25mg	1000 TAB
Surgical gloves size 7.5 sterile	50 PR
Suture synth.absorbable 2/0 2x70cm V625H	36 PCE
Syringe Luer 10ml disp.without needle	100 PCE
Syringe Luer 5ml disp.without needle	100 PCE
SyringeLuer 2ml disp.without needle	100 PCE
Tetracycline HCl 1% eye ointment 5g	50 TUB
Water for injection 10ml	50 AMP
Zinc dispersable tabl 20mg (as zinc sulphate)	100 TAB BL



## ANNEX 6: SCHEDULE OF VISITS

Day	Time	Activities	Contact Person	Telephone
Sun 9/28/08		Arrival in Kinshasa (DRC)		
Mon 09/29/08	08:00 09:00- 09:50 10:00- 10:30 10:35- 10:40 11:00- 12:00 12:30- 13:30  13:30- 14:45  15:15- 16:15 16:30- 17:15	Work station, Check emails, cell phones, etc. Briefing meeting with Health team Briefing w/ Mission Director and Exo Meeting GSO/Shipping team at JAO (US Emb) Meeting w/ PSI  Break / lunch  Meeting w/ AXxes and Georgetown University Visit at Procoki (PSI's warehouse)	Aline Aline Allyson  Binda Nzau Theresa Tapsoba  Albert Kalonji Jean Feleka	
Tue 09/30/08  Cptble PNAM 0998429801	AM 08:30- 09:30 10:30- 11:30  12:30- 13:30  14:00- 15:00  15:30- 16:30	Check emails Meeting w/ Clinton Foundation (Elya Tagar) PEPFAR Team Break / lunch  Meeting the 3 <sup>rd</sup> direction of pharmacy/national pharmaceutical program & / PNAM (Programme National d'Acces aux Medicaments) Meeting with Global Funds procurement unit ( <i>av.lukusa Imm.Fina</i> ) alain.akpadji@undp.org	Elya Tagar Laurent Kapesa  Mbeke mbekemusoka@y.fr Matamba Alain Apkadji Mme Fatumata	0817589582  0999927766  0998470444 0810704092 0817153331
Wed 10/01/08	09:00- 10:30 10:45- 12:30  12:30- 14:00  14:00- 15:00 16:00- 17:00	Check emails Meeting w/ <b>GTMA</b> Meeting w/ <b>WB</b>  Break / lunch  Meeting w/ <b>Médecins Sans Frontières</b> Meeting w/ <b>Agetraf</b>	Brigitte Capon John A. Elder  Waynes Rex Kufulula	0999982921 0993257724  0818952399

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<b>Day</b>	<b>Time</b>	<b>Activities</b>	<b>Contact Person</b>	<b>Telephone</b>
Thu 10/02/08	09:00-10:30 10:45-12:30  11:30-12:30  12:40-13:40 15:30-16:30	Check emails Meeting w/ UNICEF Meeting w/ UNFPA  Break / lunch  Meeting w/ <b>UNFPA</b> Meeting w/ <b>UE/9e FED</b>	Dr Shamwol   Pierre Shamwol Dr Mulowe	      0998630949
Friday 10/03/08  <i>Wagenia (Misson Pharma)</i>	09:00-10:00   12:30-14:00  14:00-15:00	Check emails, Meeting w/ <b>FEDECAME Team</b>  Break / lunch  Meeting w/ <b>WHO</b>	Phc. Odon   Dr Compaore	
Sat 10/04/08				
Sun 10/05/08				
Mon 10/06/08	08:00-11:00:12:00 12:15-13:15 13:15-14:30  14:30-15:00 15:00-15:30 16:00-16:30 16:30	<b>Departure to Kisantu</b> Meeting w/ CDR director & BDOM director Meeting w/ District Medical Inspector Lunch  Back to Sonabata Meeting w/ the Health zone staff in Sonabata Back to Kinshasa	Sister Emilie	
Tue 10/07/08	08:30-09:45 10:00-11:30  11:45-13:00  14:30-15:30 16:00-17:00	Meeting w/ PNMLS (WB-MAP program): Meeting w/ AIDS program (PNLS) Meeting w/  Lunch  TB progr & Action Damien, TLMI Meeting w/ Immunization program		

*Annex 6: Schedule of Visits*

<b>Day</b>	<b>Time</b>	<b>Activities</b>	<b>Contact Person</b>	<b>Telephone</b>
Wed 10/08/08	06:30-09:45 11:00-11:45  12:00-13:30  13:30-15:00  15:00-16:30  17:00	<b>Departure to Kananga</b> Meeting w/ provincial minister of health & provincial medical inspector Meeting w/ provincial drugstore director  Break lunch (in Kananga)  Meeting w/ USAID partners (AXxes, PSI)  Departure to Tshikaji		
Thu 10/09/08	08:00-11:30 12:43	Meeting w/ Tshikaji health zone staff Visit of Kalemba Mulumba health center Departure to airport <b>Back to Kinshasa</b>		
Friday 10/10/08	09:00-10:00 10:30-11:30  12:30-14:00  14:00-15:00 15:30-16:30	Meeting the 3 <sup>rd</sup> direction of pharmacy/national pharmaceutical program & / PNAM		
Sat 10/11/08		Work on briefing materials and report		
Sun 10/12/08				
Mon 10/13/08	09:00-10:00 10:30-11:30  12:30-14:00  14:00-15:00 15:30-16:30	Work on briefing materials and report		

*Assessing the Procurement, Distribution, and System-Strengthening Needs for the Pharmaceutical System in DRC, October 2008*

<b>Day</b>	<b>Time</b>	<b>Activities</b>	<b>Contact Person</b>	<b>Telephone</b>
Tue 10/14/08	10:00- 10:30	Debriefing meeting w/ the mission director	Aline	
	12:00- 13:00	Break / lunch		
	14:00- 15:00	Town check in	Aline	
	15:30- 16:30	Debriefing meeting w/ the Health Team		
		<b>Xavier Tomsej back to US</b>		
Wed 10/15/08				
Thu 10/16/08				
Fri 10/17/08				
Tue 10/21/08		Grace Adeya back to US		

## ANNEX 7: LIST OF PERSONS MET DURING ASSESSMENT

	<b>Name</b>	<b>Organization</b>
1	Steve Haykin	USAID/DRC
2	Laurent Kapesa	USAID/DRC
3	Emile Bongo	USAID/DRC
4	Lina Piripiri	USAID/DRC
5	Richard Matendo	USAID/DRC
6	Marcel Kabila	USAID/DRC
7	Michele Russel	USAID/DRC
8	Thibaut Mukaba	USAID/DRC
9	Theresa Gruber-Tapsoba	PSI/DRC
10	Jamaica Korcker	PSI/DRC
11	Tshande Kisumbule	US Embassy/GSO/Shipping
12	Maholo Mukodia	US Embassy/GSO/Shipping
13	Binda Nzau	US Embassy/GSO/Shipping
14	Roosevelt Tsewole	US Embassy/GSO/Shipping
15	Jean Feleka	PSI/Warehouse
16	Salomon Mukenge Albert	PSI/Warehouse
17	Kalonji	Project AXxes
18	Willian Clemmer	Project AXxes
19	Pelagie Nsaraza	Georgetown University/ IRH
20	Arsene Binanga	Georgetown University/ IRH
21	Esther Bamenga	Bill Clinton Foundation, DRC
22	Elga Tagar	Bill Clinton Foundation, DRC
23	Lucas Flamingni	CDC/DRC
24	Leon Motingia	CDC/DRC
25	Faustin Malele	CDC/DRC
26	Mme Fatumata	PNUD/Global Funds Procurement unit
28	Alain Akpandji	PNUD/Global Funds Procurement unit
29	Luzolo	MoH/Division of Pharmacy
30	Uteji	MoH/Division of Pharmacy
31	Matamba	National Pharmacy Program
32	Kindenge	National Pharmacy Program
33	Pierre Shamwol	UNFPA
34	Marc Tshimankinda	UNFPA
35	Dr Mulowe	EU/9e FED
36	Jean Christophe Pelissier	EU/9e FED
37	Odon Mulangu	FEDECAME
38	Jean Claude Deka	Provincial drugstore, Kisantu
39	Sr Emily Mullen	Provincial drugstore, Kisantu

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DRC, October 2008*

	<b>Name</b>	<b>Organization</b>
40	Jean René Ngombo	Provincial drugstore, Kisantu
41	Nsimbi Nsoki	Sonabata Health Zone
42	Joseph Makengele	Sonabata Health Zone
43	Mvuenga Luyeye	Sonabata Health Zone
44	Nzazi Kunda	Sonabata Health Zone
45	Nkusu Miala	Sonabata Health Zone
46	Buense Mafuta	Sonabata Health Zone
47	Aimé Mboyo	National Multisectoral HIV program
48	Gisele Mpoyi	National Multisectoral HIV program
49	Gustave Kabutakupua	Provincial Medical Inspection/Kasai oriental
50	Edmond Mulamba	Provincial Medical Inspection/Kasai oriental
51	Serge Kalume	Provincial drugstore/Kasai oriental
52	Sr Brigitte Bidwaya	Provincial drugstore/Kasai oriental
53	Salumu Tambue	PSI/Kasai Oriental
54	Crispin Batubenga	Project AXxes/Kasai Oriental
55	Bady Mwala	Tshikaji Health Zone (Kasai Oriental)
56	Bernard Ilunga	Tshikaji Health Zone (Kasai Oriental)
57	Francois Kapinga	Tshikaji Health Zone (Kasai Oriental)
58	Tarzan Ntanda	Tshikaji Health Zone (Kasai Oriental)
59	Leon Souza	Kalembe Mulunba Health Center
60	Eulalie Kasongo	Kalembe Mulunba Health Center
61	Brigitte Capon	GTMA
62	Rex Kifululuka	Agetraf
63	Endundo	Agetraf
64	Dr Compaore	WHO
65	Dr Cecile Mbotama	UNICEF
66	Odon Mulangu	FEDECAME