# Haiti Pharmaceutical Sector Technical Assistance Priorities: Technical Report

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# Haiti Pharmaceutical Sector Technical Assistance Priorities: Technical Report

Sameh Saleeb
Seydou Doumbia

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## About SIAPS

The goal of the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

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## Key Words

Haiti, technical assistance, pharmaceuticals

Systems for Improved Access to Pharmaceuticals and Services
Center for Pharmaceutical Management
Management Sciences for Health
4301 North Fairfax Drive, Suite 400
Arlington, VA 22203 USA
Telephone: 703.524.6575
Fax: 703.524.7898
E-mail: siaps@msh.org
Website: www.siapsprogram.org

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## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| CDAI | *Centre Départemental d'Approvisionnement en Intrants* |
| DPM/MT | *Direction de la Pharmacie, du Médicament et de la Médecine Traditionnelle* |
| EML | essential medicines list |
| MSPP | *Ministère de la Santé Publique et de la Population* |
| NGO | nongovernmental organization |
| NMP | National Medicine Policy |
| PAHO | Pan American Health Organization |
| PROMESS | *Programme de Médicaments Essentiels* |
| SIAPS | Systems for Improved Access to Pharmaceuticals and Services |
| SOP | standard operating procedure |
| STG | standard treatment guidelines |
| WHO | World Health Organization |
| USAID | US Agency for International Development |

## BACKGROUND

Access to medicines remains a major issue for the Haitian population. National-level statistics show that less than half the population has acceptable access to medicines. In addition, for those who have access, there is no guarantee of the quality of medicines.

For more than 10 years, the *Ministère de la Santé Publique et de la Population* (MSPP), donors, foundations, and nongovernmental organizations (NGOs) have implemented projects to ensure the availability and accessibility of essential medicines, but a lack of success has been caused by several challenges, which include the following:

- Insufficient budget allocated to MSPP
- Low income of Haitians
- High prices of the medicines provided by distributors
- Inadequacy of legislation and regulation to address realities of the situation, resulting in noncompliance and lawlessness in the national pharmaceutical market

The pharmaceutical sector suffers from the same deregulation issues as the rest of the health system. This situation creates serious anarchy in terms of safety. The perception of medicine as a source of profit is prominent, and medicines are treated as simple bargaining tools.

Pharmaceutical activities in Haiti are nominally regulated by legislative documents from 1948 and 1955. A law on pharmacy and medicines was presented to parliament in 2003 and passed by the Chamber of Representatives; unfortunately the Senate has not adopted this bill.

A document on National Medicine Policy (NMP) developed in 1997 and defining major strategic orientation for the pharmaceutical sector exists; however, the government has never officially adopted it. The overall objective for implementation of the NMP is still relevant and has been confirmed as "designed to ensure availability, accessibility, and rational use of medicines and pharmaceutical products, in general, efficacious, safe, of good quality and at affordable price by promoting the essentials medicines policy." This policy document is not well known, and defined strategies have not been implemented, except for the essential medicines program, which survives through donor and World Health Organization/Pan American Health Organization (WHO/PAHO) support. Unfortunately, the essential medicines program is completely disconnected from the national pharmaceutical sector and institutions that govern that sector.

As part of the strategy to reform the health system, the MSPP has decided to develop a new NMP. This policy is a commitment from the nation to provide quality pharmaceutical services to the Haitian population on the basis of equity and justice.

The US Agency for International Development (USAID) Mission in Haiti has been supporting the MSPP and other partners for many years to improve availability and access to quality pharmaceutical products for the Haitian population. Currently, with funding from the US

President's Emergency Plan for AIDS Relief, the local USAID Mission is assisting Haiti in the provision of HIV/AIDS commodities through the Supply Chain Management System Program. Recently, USAID/Haiti has requested technical assistance from the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program to support the Pharmaceutical Services Division of the Ministry of Health known as *Direction de la Pharmacie, du Médicament et de la Médecine Traditionnelle* (DPM/MT) in identifying priority pharmaceutical sector gaps that USAID could might provide support for the DPM/MT to address.

The SIAPS mission visited Port-au-Prince, Haiti, February 12–17, 2012, for a preliminary assessment that would contribute to the development of the NMP in the context of the revision of the National Pharmaceutical Policy.

## Purpose of Trip

To carry out an assessment to identify major pharmaceutical sector policy gaps and issues that predominantly affect access and use of essential medicines as well as key public health products in Haiti with a view to addressing them in a revised NMP.

## Methodology

### *Identification of Key Products and Reports*

SIAPS staff identified key assessment, policy, planning, and strategy documents that may have bearing on the revision of the NMP.

### *Interviews with Stakeholders*

The SIAPS team developed an interview guide based on WHO recommendations for NMP development. Several meetings were held with MSPP staff and pharmaceutical sector stakeholders and decision makers, donors, international health agencies, private sector representatives, and training institutions. The DPM/MT with support from the Supply Chain Management System Program assisted in identifying stakeholder organizations and in calling for the meetings. In many instances, the DPM/MT provided the venues and the necessary support for these meetings.

These interviews provided important information related to key priority gaps in the pharmaceutical sector affecting access and appropriate use of essential medicines in Haiti that would need to be considered in the revision of the NMP.

## FINDINGS

The main findings from key informant interviews of significant pharmaceutical sector issues, themes, and gaps that need to be considered in the NMP revision are summarized below, according to the elements of the WHO guideline document for NMP development.

### Policy/Legal Framework

#### *Regulation*

Haiti's pharmaceutical sector is governed by a law created in 1955. The law is outdated and is not in line with country's current pharmaceutical practice. For example, the current legislation does not address the major growing concern about the informal sector and street vendors of medicines, which are key priorities. In addition, the role of the DPM/MT as a regulatory entity needs to be strengthened. This will allow major functions such as registration and market authorization, inspections, and management of donations to be adequately enforced.

Regulatory guidelines dating to 2009 are currently under revision. These guidelines are not always available to DPM/MT staff. These documents need to be disseminated more widely to staff so they can understand their role and to other authorities for appropriate enforcement.

The DPM/MT does not have sufficient resources (human, competencies, and finance) to fulfill the mandate and the objectives that have been conferred on it. This situation seriously compromises the ability of the DPM/MT to play its critical role in regulating the pharmaceutical sector. To protect the population, the DPM/MT needs to be given the authority to be able to sanction illegal or dangerous practices.

The last NMP dates from 1997, but this document was never adopted by the parliament. Updating the NMP to be in line with current pharmaceutical practice is a high priority.

#### *Registration/Importation Authorization*

The registration of products in Haiti is governed by a law passed in 1948 that requires all products to be registered. Unfortunately, this law has never been enforced. As a result, the pharmaceutical sector suffers from poor implementation of regulations, including a lack of enforcement of licensing, inspection, and importation of medicines.

The product registration process in Haiti is cumbersome; it suffers from long delays and has a considerable backlog. The registration procedure for new products is excessively complicated.

Delays are also long for importers to obtain import authorizations, which delays and excludes authorized quality products from entering the local market, thus opening room for nonauthorized products. Regulatory systems are very weak and allow the importation of medicines of unknown

quality as well as the distribution and the selling of medicines by unqualified individuals in the private sector.

### *Inspections*

Inspection is a very important component to ensure the quality of medicines, influencing a wide range activity from manufacturing to delivery.

The DPM/MT conducts inspections to ensure that all manufacturing operations, importation, distribution, and dispensing of medicines comply with standards and procedures, operating regulations, and quality assurance requirements. However, the DPM/MT's ability to conduct inspections is very limited because of lack human resources, materials, and logistics. Presently, the DPM/MT has only one pharmacist in charge of inspection. The lack of resources allocated to this service makes inspection nearly nonexistent. In addition, that DPM/MT has no authority to enforce these regulations, including imposing sanctions.

## Quality Control

Quality assurance covers all activities designed to ensure that consumers and patients receive products that meet specifications and existing standards of quality, safety, and efficacy.

The quality of medicines available in Haiti is a cause of great concern. No regular mechanism exists for quality control of medicines or products either manufactured locally or imported. The country does not have a quality control laboratory, and it does not use the services of laboratories in neighboring countries. The absence of quality control capacity in Haiti creates a fertile ground for counterfeit and substandard medicines.

The problem of pharmaceutical waste management is another serious issue. Haitian hospitals do not have incinerators to dispose of unusable and expired products.

## Selection

An essential medicines list (EML) has been developed by level of health care delivery as a valuable tool to control the use of medicines in the public sector, but it has not yet been disseminated. Chronic disease products and consumables are not included in the EML.

Treatment standards for providing health care services are available only for public health programs such as malaria, HIV/AIDS, reproductive health, tuberculosis, integrated management of childhood illnesses, and sexually transmitted infections. Haiti has no comprehensive, nationwide standard treatment guidelines (STGs). The STG is a reference intended to assist the health worker in choosing the appropriate pharmaceutical treatment after the correct diagnosis has been made. The availability and the use of STGs by health workers encourage uniformity in disease management, thus promoting and maintaining the rational use of drugs in the health care delivery system.

## Procurement and Distribution

### *Private Sector*

The private sector in Haiti is a major source of care. These pharmaceutical establishments do not always conform to good practice norms for stocking and distribution.

The following gaps are observed at the level of the sale of medicines in the private sector:

- Some nonauthorized products are sold in pharmacies.
- Good storage conditions are not always respected.
- Managers do not always have good practices for storage, distribution, and inventory management.
- Tasks and responsibilities are not clearly defined.
- Staff is not always qualified and well trained.

The absence of a Pharmacy Council in Haiti has created a situation in which private pharmacies are typically managed and staffed by nonprofessionals with little knowledge of medicine and therapeutics, which leads to severe irrational use practices.

No regulation exists of geographic distribution of pharmacy establishments in the country. Therefore, most pharmacy facilities are located in urban areas, creating a problem of geographic accessibility in peri-urban and rural areas.

The association of pharmaceutical product importers, *Association Nationale des Importateurs et Distributeurs des Produits Pharmaceutiques*, includes less than half of the country's importers.

The estimated number of pharmacies is about 500 in the metropolitan region. Of these, only 200 are registered. The private pharmacies supply themselves at the level of local distributors. Some of them buy medicines from the informal market.

### *Public Sector*

#### *Programme de Médicaments Essentiels (PROMESS)*

PROMESS is a WHO/PAHO-supported central medicine store created in 1992 to undertake medicine procurement, storage, and distribution to the public sector in Haiti. PROMESS provides services for donor agencies in terms of receiving, storing, and distributing donated products. Although PROMESS was created to provide for essential medicines needs of the public sector, no official instrument requires health facilities and peripheral depots to procure their supplies from PROMESS as a sole source. Because health facilities and depots can procure from private suppliers, PROMESS faces stiff competition from private suppliers who can offer attractive packages that PROMESS cannot afford because of its status as a WHO project mainly supplied by donors as well as the amount of cost-recovery products in stock.

PROMESS procures medicines, medical supplies, and equipment through WHO/PAHO. It submits its requirements, and the actual procurement is conducted by PAHO in Washington, DC. No procurement is done in country. PROMESS submits its orders with the available funds through WHO/PAHO on an as-needed basis. It buys supplies based on availability of funds and existence of stock-outs. The products procured by PROMESS are sold to depots and health facilities under a cost-recovery plan. PROMESS serves peripheral depots or warehouses, NGOs and similar groups, and specialized services such as the State University Hospital.

Although it has the mandate for supplying the peripheral depots and health facilities, PROMESS is not integrated into the national public health system.

### *Departmental Drug Depots (CDAIs)/Peripheral Depots*

The *Centres Départementaux d'Approvisionnement en Intrants* (CDAIs) are the link between the central medicine store and health institutions. They are supplied by PROMESS and serve public health and mixed institutions of the different departments. The CDAIs constitute a very important link in the medicine distribution chain, but they do not have any legal status ensuring their autonomy for sounder management.

The status of the peripheral depots is a constraint for rationalizing the supply procurement and distribution network in the public sector. Neither the CDAIs nor the depots have any legal documents stating and supporting their mode of operations. The absence of a homogeneous organization negatively affects availability of and access to essential medicines in health facilities.

The peripheral depots have been unable to meet the challenges of providing procurement efficiently because of a number of structural and operational problems. Weak transportation and lack of communication between the different levels of the health system make monitoring stock levels and dealing with shortages difficult. In most facilities, the selected medicines requested by the MSPP are not always available.

### *Health Institutions*

Hospital pharmacies, health centers, and dispensaries are health institutions that supply themselves at the level of the CDAIs. They can also procure directly from nonassured sources and through a noncompetitive process.

Institutional pharmacies experience the same management difficulties as the CDAIs. They are for the most part managed by a social service pharmacist who is not trained in pharmaceutical management.

### *Commodity Management*

The pharmaceutical supply system currently operates on central medical store principles. Under this system, procurement and distribution of medicines are centralized, with key functions of selection, quantification, and procurement determined by WHO/PAHO. Medicines ordered

follow different circuits of distribution to reach clients: the public circuit through the peripheral depots, the partner institution circuits, and their remote facilities. Public facilities use their own logistical capabilities to get their medicines whereas those from the NGO network are mostly supplied by partner institutions.

PROMESS is the central point that supplies health institutions countrywide in essential medicines and products.

With respect to commodity management, an analysis of the current distribution system was conducted in the framework of the *Projet de Création du Réseau de Distribution des Intrants* in May 2008, which identified the following problems:

- Passive medicine distribution system
- Frequent stock-outs at PROMESS
- Insufficient human resources, both qualitative and quantitative, in certain CDAIs
- Lack of communication between the following:
    - PROMESS and regulatory authorities
    - PROMESS and the CDAIs
    - The CDAIs and health institutions
    - Leaders of public health programs and the DPM/MT in charge of the essential medicines program
- Poor quantification because of lack of standardized management tools
- Administrative complexity in the distribution system resulting from current approval procedures
- Existence of many parallel distribution systems put in place by partners and donors
- Lack of coordination among donors and between the donors and MSPP leaders in quantifying specific program needs
- Ineffective quantification mechanisms that do not allow for demand to be satisfied; lack of technical capacity in certain cases to define needs and to verify their proper use
- Absence of a standard framework for the collection and reporting of information in the logistics system
- Absence of CDAIs' legal status
- Currently unsustainable distribution system because of the legal status of PROMESS

## Donations

The management of donations is an important issue in Haiti. According to stakeholders interviewed, following the most recent natural catastrophes, Haiti received several donations of which more than half were expired and were not found on the EML.

Another problem is the accumulation of unused medicines that Haiti now has to deal with in terms of waste management. Donor countries need to send the list of medicines beforehand so they can obtain authorization from the national health authorities before sending donations.

Another persistent problem raised is the time that it takes for containers of donations to be released from customs. Steps need to be taken with the customs administration so that one can place humanitarian containers apart to avoid complications and to facilitate their release.

## Rational Use

The rational use of medicines faces significant challenges related to prescribing, dispensing, and adherence to treatment. The unavailability of essential medicines, the lack of objective information, the influence of advertising on prescribers and consumers, and the absence of a Drug and Therapeutics Committee offer the "perfect storm" for irrational drug use in Haiti.

Irrational prescribing is common in Haiti because of lack of formal training on standards of prescribing and dispensing of medicines for health care providers and absence of continuing education programs for health professionals on drug therapy and rational drug use. At health institutions, prescribers do not usually prescribe by generic name and are more interested in promoting innovators.

Health information is insufficient, and most of the information coming from laboratories (pamphlets, medical sales, and so on) is not adequate. There is no control on advertising materials or messages for the public audience. The DPM/MT does not control promotional advertising of medicines.

A national EML was developed in 2003 and validated during a validation workshop organized by the MSPP program managers and health professional organizations. It has been revised recently but has not been disseminated yet.

The absence of a Pharmacy Council in Haiti has created a situation in which private pharmacies are typically managed and staffed by nonprofessionals with little knowledge of therapeutics and the pharmaceutical sector, leading to severe irrational use practices.

The informal pharmaceutical market with its multiple consequences in public health, including therapeutic failures, poisonings, and drug resistance has taken on alarming proportions in Haiti. This illicit market is difficult to assess. Medicine peddlers operate everywhere in the country, including in the public transportation system, without any impunity. A study is needed to better understand this sector.

## Human Resources

The implementation of the NMP requires qualified human resources in sufficient numbers: pharmacists, pharmacy and laboratory technicians, and pharmacy assistants. However, the pharmaceutical sector in Haiti is characterized by a notable deficit in human resources both in capacity and numbers. Only pharmacists are trained in Haiti. There is no school for pharmacy technicians and for pharmacy assistants. This situation seriously compromises the ability of the DPM/MT to play its critical role in regulating the pharmaceutical sector. Currently, the state university graduates only about 30 pharmacists per year, a number quite insignificant in a population of 10 million people. Moreover, youths see this profession as a low-paying job in comparison to others.

Challenges include the following:

- Lack of skilled staff in numbers and competencies
- Lack of diversified cadres in the pharmaceutical sector
- Lack of continuing professional development programs
- Lack of specialists in pharmacy production, pharmacology, and so on
- No school for pharmacy assistants and pharmacy technicians

## Information Systems

A pharmaceutical management information system is completely missing. No information is collected or available about the importation or production of medicines in Haiti. No information-sharing mechanism exists: each partner has its own information system, and no coordination body has been established, resulting in stock-outs or overstocks in country. The lack of pharmaceutical management information does not allow proper quantification to meet country needs or monitoring of stocks and expiries of commodities.

## Medicine Pricing and Financing

Haiti has no universal national policy to provide medicines free of charge at public primary care facilities. However, some public facilities, at all levels of care (primary, secondary, and tertiary) provide medicines free of charge, but most sell medicines to patients.

At all levels of care in the Haitian health care system, no standardization was found regarding what fees are charged to patients. The fees at all levels may include consultation fees, dispensing fees, or flat fees for medicines, flat-rate copayments for medicines, or percentage copayments for medicines. At some facilities no fees are charged for any level of care. Prescribers in the public sector frequently dispense medicines when available at the institution’s pharmacy, while prescribers in the private sector occasionally dispense medicines.

In Haiti, some of the population, mostly government employees, has public health insurance, which covers some medicines. Some of the population has private health insurance, which covers some medicines.

The government does not set the price of any originator brand products or any generic products. The national EML is not being used for public or private supply. Setting prices is not part of market authorization.

Haiti does not have a national medicine price monitoring system for retail or patient prices. There are no regulations mandating retail or patient medicine price information to be made publicly accessible even when the maximum profit margin is (on paper) fixed at about 40 percent of the purchase price. There is no price structure for essential medicines.

## Patient Safety/Pharmacovigilance

The aim of pharmacovigilance is to enhance patient care and patient safety in relation to medicine quality, prescribing errors, and adverse drug effects. All of these, if not monitored, have severe consequences on patient safety.

Haiti has no pharmacovigilance system or postmarketing surveillance or public education program. All of the partners with whom the SIAPS team met emphasized the need to put in place a pharmacovigilance system.

## Local Production

Three local production laboratories—Caribbean Canadian Chemical (4C), Farmatrix, and Pharva—and 33 import agencies distribute medicines to medicine depots and to pharmacies. It was suggested that a coordination mechanism for local manufacturers and the essential medicines program should be created to ensure that essential medicines are prioritized for local production.

No strategy exists to encourage local production of medicines; such a strategy could encourage diversification of the types of products produced locally to meet the local market needs. A government policy that encourages local production would positively affect the diversification of types of products produced locally to meet the local market needs. Such a policy could include tax preferences on commodities (such as raw materials, reagents, and consumables). Representatives of local manufacturers also requested that the government mediate and support discussions with WHO to facilitate good manufacturing practice certification for these companies, hence improving their chances for participation in the export market.

National political will to support local production is highly desirable to promote geographic and financial accessibility.

## Bilateral and Regional Cooperation

Presently, no cooperation exists with other countries with respect to pharmaceutical areas. Regional collaboration in the area should be encouraged, for example, quality control (results from certain bad batches); information regarding prices would be highly beneficial.

## RECOMMENDATIONS

The visit was very valuable in providing necessary information to guide the revision of Haiti's NMP. The interviews were also instrumental in highlighting many gaps within the pharmaceutical sector. Although the duration of the visit did not allow a full detailed analysis of the sector, it clearly highlighted priority gaps. The following issues are the key priorities that the SIAPS team recommends the DPM/MT should address in the short term in addition to the NMP revision:

- Although the update of the NMP is clearly a well-identified priority for the DPM/MT, the SIAPS team recommends that a stakeholder engagement process be built into the revision process to maximize stakeholders' buy-in.
- Develop a pharmaceutical strategic plan. Once the NMP is reviewed and approved, a sector strategic plan will be critical to guide its implementation. The team also recommends that a defined group be identified to oversee the strategic plan development and later its implementation.
- As a priority, establish a commission tasked to analyze the current status of medicine registration, inspection, and quality control, including opportunities for regional cooperation. Such analysis will be essential to inform policy implementation and to guide improvement activities targeted to these critical regulatory functions.
- Disseminate the revised EML: an updated list is already available. Dissemination to service delivery level can support good local procurement practices and rational use of essential medicines.
- Analyze the status of the DPM/MT standard operating procedures (SOPs), including organogram, procedures, and functions, and determine the need for any updating to reflect key regulatory functions. Such documentation of SOPs will be key in developing common understanding among stakeholders about the role of the DPM/MT and the responsibilities of its staff.
- Analyze the current supply chain system channels for essential medicines, and establish a mechanism for overall coordination including for donors products and donations. Such a mechanism can be subsumed in the current initiative for the development of a unified supply chain system.
- Establish a national drug therapeutic committee to assist in the development of national STGs (other than those for vertical programs) to promote rational use of medicine.
- Conduct a situation analysis of the informal medicine sector with focus on street medicine vendors. A clear understanding of the contributing factors is essential to inform any future legislation and also to develop potential public education messages.