



# Assessment of the Medicines Regulatory System in Angola: Report



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## **Assessment of the Medicines Regulatory System in Angola: Report**

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Printed: June 2013



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The SIAPS logo consists of the word "SIAPS" in a bold, green, sans-serif font, followed by a stylized blue figure of a person with arms raised, similar to the USAID logo.

This report is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of cooperative agreement number AID-OAA-A-11-00021. The contents are the responsibility of Management Sciences for Health and do not necessarily reflect the views of USAID or the United States Government.

## **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.

## **Recommended Citation**

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Thumm, M., P. Gaparayi, W. Goredema, and D. Tjipura. 2013. *Assessment of the Medicines Regulatory System in Angola: Report*. Submitted to the US Agency for International Development by the Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Arlington, VA: Management Sciences for Health.

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## ACRONYMS AND ABBREVIATIONS

ADR	adverse drug reaction
AIDS	acquired immunodeficiency syndrome
ANVISA	Agência Nacional de Vigilância Sanitária (National Health Surveillance Agency of Brazil)
CTNM	Comissão Técnica Nacional de Medicamentos (National Technical Committee for Medicines)
DIF	Departamento de Inspeção Farmacêutica (Department of Pharmaceutical Inspection)
DNME	Direção Nacional de Medicamentos e Equipamentos (National Directorate of Medicines and Equipment)
GMP	Good Manufacturing Practice
HIV	human immunodeficiency virus
IGS	Inspectorate General of Health (Inspeção-Geral da Saúde)
MINSÁ	Ministry of Health (Ministério da Saúde)
MSH	Management Sciences for Health
NPP	National Pharmaceutical Policy
PNME	Programa Nacional de Medicamentos Essenciais (National Essential Medicines Program)
RSAT	Regulatory Systems Assessment Tool
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	standard operating procedure
SPS	Strengthening Pharmaceutical Systems
UMC	Uppsala Monitoring Centre
USAID	US Agency for International Development
USD	US dollars
WHO	World Health Organization

## ACKNOWLEDGMENTS

We are grateful to the Angolan Ministry of Health (Ministério da Saúde; MINSa) and its National Directorate of Medicines and Equipment (Direcção Nacional de Medicamentos e Equipamentos; DNME), National Essential Medicines Program (Programa Nacional de Medicamentos Essenciais; PNME), and the Inspectorate General of Health (Inspecção-Geral da Saúde; IGS) for the cooperation, leadership, and direction they provided to make this assessment a success. We acknowledge the following MINSa officials and all local counterparts and stakeholders who contributed to the assessment—

Dr. Boaventura Moura, Director, DNME

Prof. Dr. Miguel dos Santos de Oliveira, Inspector General of Health, IGS

Ms. Isabel Margareth Malungue, Chief of the Department of Pharmacovigilance, DNME

Dr. Avelino Manacas, Director of the PNME

Dr. Pombal Mayembe, Chief of the Department of Medical Products and Sanitation, DNME

The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program would also like to thank the US Agency for International Development (USAID)/Angola staff for being very supportive and helpful throughout the process, specifically Dr. Rachel Jean-Baptiste (Health Team Lead) and Domingas Canhanga (USAID/SIAPS Activity Lead).

Data were collected by Melissa Thumm, assisted by Patrick Gaparayi (SIAPS/Angola) and Michael Ofeke (SIAPS/Angola). Wonder Goredema, Dinah Tjipura, and Jude Nwokike provided technical guidance and oversight from the SIAPS home office in Arlington, Virginia.

Finally, we wish to express our sincere appreciation to the SIAPS Program, Management Sciences for Health, and USAID for providing leadership, technical support, and funding for the assessment.

## EXECUTIVE SUMMARY

### Background

The burden of malaria, HIV and AIDS, and tuberculosis in Angola and the investment of both the national government and international donors, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the US Agency for International Development (USAID)—through the US President’s Malaria Initiative and the US President’s Emergency Plan for AIDS Relief—to improve the availability and use of medicines and other health commodities for the effective diagnosis, treatment, and prevention of these priority diseases have highlighted the need to strengthen the regulatory system in place to ensure the products are safe, effective, and of good quality.

The Ministry of Health (Ministério da Saúde; MINSA)’s National Directorate of Medicines and Equipment (Direccao Nacional de Medicamentos e Equipamentos; DNME) is responsible for regulating medicines and other pharmaceutical products in Angola in collaboration with the Inspectorate General of Health (Inspecção-Geral da Saúde; IGS). Preliminary reports indicated that the regulatory system was not fully functional or operating effectively and thus needed assistance.<sup>1</sup> As a first step toward providing technical support and identifying additional sources of assistance to strengthen the regulatory system, the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program, which has been providing support to the DNME since 2005 in pharmaceutical management, particularly supply chain management, conducted an assessment of the system and DNME’s capacity to implement it.

### Methodology

A comprehensive assessment of the current regulatory system in Angola and the capacity of the DNME was conducted from October to November 2012, with USAID funding to the SIAPS/Angola program. The SIAPS team used the Regulatory Systems Assessment Tool (RSAT),<sup>2</sup> a baseline assessment tool developed by the Strengthening Pharmaceutical Systems (SPS) Program, to examine the status of the national medicine regulatory systems and the capacity of the national regulatory authority to effectively ensure the safety, efficacy, and quality of medicines. The RSAT assessment involves the review of key documents and collection of data using questions that examine the primary regulatory functions as well as overarching areas related to governance and management. Findings generated from the RSAT assessment are intended to facilitate the identification of weaknesses, gaps, strengths, and opportunities for strengthening national regulatory systems and capacities, which in turn can be used to develop options and key recommendations.

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<sup>1</sup> World Health Organization (WHO) and Southern African Development Community (SADC). 2009. “Country Data Profile on the Pharmaceutical Situation in the Southern African Development Community (SADC): Angola.” World Health Organization. <http://www.who.int/medicines/areas/coordination/Angolaweb.pdf>.

<sup>2</sup> Strengthening Pharmaceutical Systems (SPS) Program. Forthcoming. *Regulatory Systems Assessment Tool*. Arlington, VA: Management Sciences for Health.

The assessment in Angola covered the main components of the regulatory system, including primary functions (product registration, licensing, inspection, quality control, and pharmacovigilance) as well as medicine legislation, organizational structure and systems, and governance. The specific objectives were as follows—

- Identify strengths, weaknesses, gaps, and opportunities in the regulatory system
- Make recommendations for strengthening the system
- Assist partners in defining and reaching consensus on their priorities based on evidence
- Provide evidence that the DNME can use to advocate for the additional technical support and funding needed to improve the regulatory system in Angola
- Create a baseline for measuring the system’s performance and progress over time

## **Results**

### ***Legal Framework***

Angola has a National Health Policy that covers pharmaceuticals as well as a comprehensive National Pharmaceutical Policy (NPP) adopted in 2010; however, it does not have a current Pharmaceutical Law. A law has been developed but has not yet been approved. Numerous regulations are still needed to solidify the legal mandate for a comprehensive regulatory system. The DNME has identified the need for regulations for medical devices, traditional medicines, laboratory reagents, pharmacovigilance, the quality assurance system, advertising and promotion, labeling, and cosmetics and personal hygiene products. Legislation and regulations related to national manufacturing and good manufacturing practices do not yet exist to guide and ensure the quality of national manufacturing operations currently in development.

### ***Structure and Governance***

The DNME currently operates as a national directorate within MINSÁ. However, one of the objectives in the Health Development Plan’s Program for Pharmaceutical Development is to transform the DNME into an autonomous National Institute for the Regulation of Pharmaceuticals and Health Products by 2015, to serve as the national regulatory authority. Approval for the creation of a new autonomous regulatory authority has not yet been officially granted. The DNME’s current structure includes only one committee that contributes to the regulatory functions: the National Technical Committee for Medicines (Comisso Tcnica Nacional de Medicamentos; CTNM); more committees are needed to improve representation in regulatory decision making and to capitalize on the expertise of professionals with relevant specialties who are not on staff at the DNME. Although provincial and local organizations are included in the DNME’s organogram, very few of the DNME’s regulatory activities are carried out by peripheral-level staff. The system is highly centralized, which places a heavy burden on the relatively small central-level staff, increases the cost of conducting activities in the provinces on account of travel expenses, and poses significant challenges to achieving full geographic coverage of the country by the regulatory system.

The DNME has a 10-year strategic plan outlined in the Health Development Plan's Pharmaceutical Development Program from May 2012. The plan focuses on five goals or objectives—

- Increase the availability of essential medicines
- Increase the population's financial access to medicines
- Assure the quality of dispensed medicines
- Promote the rational use of medicines
- Reinforce coordination in the pharmaceutical sector

For each of these goals, the DNME has defined strategies, activities, indicators, partners (responsible institutions), and implementation timelines.

Access to pharmaceutical information, including regulatory decisions, is limited by the absence of appropriate platforms for disseminating information and making it readily available to health professionals, patients and consumers, the public, and other stakeholders. The DNME does not have its own website or a webpage on the MINSA website. Furthermore, bulletins are not published and distributed on a regular basis.

### ***Registration***

Although legal provisions require pharmaceutical products to be registered by the DNME before they are allowed into the country and distributed, pharmaceutical products are not currently being registered; putting the registration requirement into practice depends on government approval, which has been pending for two years. In preparation for the implementation of a product registration system, the DNME has developed the necessary instruments, including tools and guidelines; however, the Registration Unit has not developed a rollout plan that outlines how the system will be progressively and strategically introduced and scaled up once the approval is granted and registration begins so that will not overwhelm the system and unit. As acknowledged by the DNME, the current staff within the Registration Unit (four total: two pharmacists, one pharmacy technician, and one administrative support) is insufficient given the upcoming increase in workload and skill level required to perform the tasks. An information system, including a database, for registration applications and approved products has not been developed and adopted yet.

### ***Licensing***

Licensing is required for private retail pharmacies, which are issued a license for three months (provisional, pending submission of all required documents), one year (all documents submitted), or two years (all documents submitted and requirements met); however, the DNME licensing unit does not issue any other types of licenses for pharmaceutical entities, personnel, imports and exports, or products. Inspections are required for licensing; however, insufficient resources (including staff and means of transportation) prevent the centralized Licensing Unit from consistently inspecting all premises applying for licenses within the legally mandated period of

two months from the time of submission. The information system for managing data on licenses is reportedly very basic and cannot easily monitor the status of licenses.

### ***Inspection***

The mechanisms for coordination and communication between the Department of Pharmaceutical Inspection (Departamento de Inspecção Farmacêutica; DIF) at the IGS and the other departments involved in the regulation of medicines at the DNME do not appear to be well defined or formalized—or as strong, effective, or efficient as they need to be to ensure adequate integration of the regulatory system’s interdependent functions, timely information exchange, and rapid responses to urgent issues, particularly given the extensive scope and importance of the DIF’s functions within the system. As acknowledged by the IGS, the DIF is understaffed with 33 total staff members at the central level, only 9 of whom are pharmacists; 2 inspectors (pharmacists or pharmacy technicians) per province; and 1 inspector (pharmacist or pharmacy technician) per municipality. Although plans are in place to start Good Manufacturing Practice (GMP) inspections of manufacturers, all of which are outside the country at present, they are not currently conducted.

### ***Pharmacovigilance***

Based on the limited scope of pharmacovigilance activities currently supported and implemented by the DNME’s Department of Pharmacovigilance, the country does not yet have a comprehensive or effective national pharmacovigilance system in place, nor does it have a framework to guide the development of such a system. The legislation has been drafted that outlines the legal provisions and regulations for pharmacovigilance, but it has not yet been approved, and the department is still in the process of drafting key guidance documents, such as guidelines and standard operating procedures (SOPs), for its activities.

Reporting of adverse drug reactions (ADRs) appears to be low: no reports were received in 2011, and only six reports were received in 2012 (up to October); ADR report investigation and follow-up tends to be high for reports received from Luanda, but very low for reports received from the provinces, because of limited human and financial resources. Currently, no active surveillance activities are being implemented to monitor medicine safety, particularly of medicines with high risk profiles. The dissemination of information on medicines, and particularly medicine safety issues, is limited; no bulletins have been issued since 2010 because of delays in approval, and the department does not have a website through which it can distribute information electronically.

### ***Quality Control***

Angola does not currently have a national quality control laboratory for medicines, although plans are in place to develop a level I laboratory with the capacity to do basic testing specifically for medicines, which will be further supported by a national level III laboratory with the capacity to do more extensive and definitive testing. At present, products that need to be tested are sent to Infarmed or a private laboratory in Portugal or to the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária; ANVISA) in Brazil. The DIF has ten mini-labs (five

in Luanda), which are used to screen medicines for quality, primarily at the main ports and other points of entry; however, they are insufficient to cover all provinces in the country.

## **Options and Recommendations**

### ***Legal Framework***

- Develop a plan and timeline for developing the regulations currently missing from the legal framework for the regulatory system.

### ***Structure and Governance***

- Conduct an options analysis of the various regulatory structures under consideration (e.g., governmental, semi-autonomous, and autonomous).
- Conduct costing analysis of current regulatory operations.
- Review the strategic plan, development plan, and annual work plan(s) to identify, define, and coordinate the DNME's technical assistance needs.
- Increase and strengthen the role of committees in the regulatory structure and framework.
- Explore options for decentralizing some regulatory functions and tasks.
- Improve the supply and demand for pharmaceutical information.

### ***Relations with Other Regulatory Authorities***

- Maintain active communication, participation, and coordination with the Southern African Development Community, the Southern African Regional Programme on Access to Medicines and Diagnostics, and the African Medicine Regulatory Harmonization.
- Establish agreements or memoranda of understanding with other regulatory authorities in the region.

### ***Registration***

- Develop a rollout plan for the registration of medicines.
- Identify an appropriate electronic information system for registration.

### ***Licensing***

- Increase the human or financial resources available for carrying out inspections as part of the licensing process.

- Identify and implement a more sophisticated information system for licensing that facilitates monitoring of license expiries and renewals.
- Advocate for and support the DNME to become the sole provider of the importation licenses and visas for all imported medicines and other pharmaceutical products.

### ***Inspection***

- Assess the efficiency and effectiveness of established mechanisms for coordination and communication between the IGS and the DNME.
- Develop the capacity of the DNME and the IGS to guarantee the quality of national manufacturing of medicines.

### ***Quality Control of Medicines***

- Conduct a study of the quality of medicines in the country with the aim of better understanding the scale and nature of the problem.
- Develop a plan for medicine quality monitoring.
- Enlist the technical support of a specialized partner to assist with the physical design and setup of the national medicine quality control laboratory.

### ***Pharmacovigilance***

- Develop and adopt a framework for a comprehensive national pharmacovigilance system.
- Continue strengthening voluntary notification of ADRs and suspected low-quality products.
- Explore opportunities and potential mechanisms for the active surveillance of medicine safety issues.

### ***Financing***

- Analyze the financial sustainability of the proposed autonomous medicine regulatory authority.

### **Conclusion**

The DNME has a clear vision for strengthening its capacity to be an effective and fully functional national regulatory authority. Many of the essential structural components of a functional regulatory system are in place, in progress, or planned, and well-defined strategic and work plans have been developed and documented to guide the strengthening of the DNME's capacity to perform its technical functions. Although opportunities still exist to improve upon the plans, the main challenge appears to be the operationalization of the structures, plans, and tools that have already been developed but not implemented, because a combination of factors related

primarily to funding, technical support, and political priority. Advocacy and “sensitization” efforts aimed at stakeholders, ranging from high-ranking state officials to pharmaceutical industry representatives to academia and other stakeholders in the pharmaceutical and health sectors, including patients and consumers, is needed to generate support for and speed up some of the changes and reforms that are being either proposed or implemented. The DNME will undoubtedly require additional technical assistance and funding to ensure that the changes and improvements do not overwhelm the system and are implemented effectively.

## BACKGROUND

Angola is an upper-middle-income country with a population of 19.6 million.<sup>3</sup> The gross national income per capita is USD 3,830,<sup>4</sup> with an estimated 36 percent of the population living below the national poverty line and 26 percent in extreme poverty.<sup>5</sup> Angola ranks 148 of 187 countries worldwide on the Human Development Index.<sup>6</sup>

The adult mortality rate for ages 15–60 years is 364 per 1,000 population, and the under-five mortality is 161 per 1,000 live births, resulting in a life expectancy of 52 years.<sup>7</sup> It is estimated that communicable diseases are the cause of 79 percent of years of life lost. HIV and AIDS prevalence is 20 per 1,000 adults 15–49 years of age, tuberculosis prevalence is 411 per 100,000 population,<sup>8</sup> and approximately 1.6 million cases of malaria are reported annually, resulting in approximately 7,000 reported deaths.<sup>9</sup> Pneumonia and diarrhea are the second and third leading causes of death in children under five years of age, representing 17 percent and 15 percent of deaths, respectively, after “other diseases” (19 percent).<sup>10</sup>

Based on the country’s revised constitution, the government of Angola has a stated responsibility to promote universal and free primary health care. In accordance with this goal, all medicines distributed through the public health sector are provided to patients free of charge. In 2010, the government budget from the General State Budget for the procurement of medical products was USD 121.4 million, representing nearly 7 percent of the total MINSa budget.<sup>11</sup> It was reduced for each of the three years prior to 2010. Essential pharmaceutical commodities are also procured by multiple international donors: the United Nations Population Fund procures reproductive health kits and contraceptives; USAID procures malaria medicines; and the United Nations Children’s Fund and the World Health Organization procure antiretrovirals, mosquito nets, and vaccines through Global Fund to Fight AIDS, Tuberculosis and Malaria mechanisms. The pharmaceutical profile of Angola is presented in table 1.

The burden of malaria, HIV and AIDS, and tuberculosis in Angola, combined with the investment of both the national government and international donors—such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and USAID (US President’s Malaria Initiative and US President’s Emergency Plan for AIDS Relief)—to improve the availability and use of medicines and other health commodities for the effective diagnosis, treatment, and prevention of priority

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<sup>3</sup> World Bank, Data by Country, 2011, <http://data.worldbank.org/country/angola>.

<sup>4</sup> World Bank, Data by Country, 2011, <http://data.worldbank.org/country/angola>.

<sup>5</sup> United Nations Development Programme (UNDP), “Angola,” Poverty Reduction, 2012, <http://mirror.undp.org/angola/Poverty%20Reduction.htm>.

<sup>6</sup> UNDP, “Angola,” Poverty Reduction, 2012, <http://mirror.undp.org/angola/Poverty%20Reduction.htm>.

<sup>7</sup> World Health Organization (WHO), “Angola: Health Profile,” 2013, <http://www.who.int/gho/countries/ago.pdf>.

<sup>8</sup> WHO, “Angola: Health Profile,” 2013, <http://www.who.int/gho/countries/ago.pdf>.

<sup>9</sup> WHO, Global Health Observatory Data Repository, “Angola Statistics Summary (2002–Present),” <http://apps.who.int/gho/data/view.country.3300>.

<sup>10</sup> WHO, “Angola: Health Profile,” 2013, <http://www.who.int/gho/countries/ago.pdf>.

<sup>11</sup> Connor, Catherine, Denise Averbug, and Maria Miralles. July 2010. *Angola Health System Assessment 2010*. Bethesda, MD: Health Systems 20/20, Abt Associates Inc.

diseases, highlights the need to strengthen the regulatory system to ensure the products are safe, effective, and of good quality.

MINSAs DNME is responsible for regulating medicines and other pharmaceutical products in Angola in collaboration with other MINSAs partners, including the IGS. Preliminary reports indicated that the regulatory system was not fully functional or operating effectively and thus needed assistance.<sup>12</sup> The USAID-funded SIAPS Program and its predecessors—the SPS and Rational Pharmaceutical Management Plus programs—have been providing support to the DNME in pharmaceutical management since 2005, particularly in the area of supply chain management. As a first step toward providing technical support and identifying additional sources of assistance to strengthen the regulatory system, USAID through SIAPS conducted an assessment of the system and of the DNME’s capacity to implement it to identify key recommendations for strengthening it.

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<sup>12</sup> WHO and SADC. 2009. “Country Data Profile on the Pharmaceutical Situation in the Southern African Development Community (SADC): Angola.” World Health Organization. <http://www.who.int/medicines/areas/coordination/Angolaweb.pdf>.

**Table 1. Angola's Pharmaceutical Profile**

<b>Pharmaceuticals index</b>	
Population (millions, 2011) <sup>a</sup>	19.62
Gross national income per capita (USD, 2011) <sup>a</sup>	3,830
Total expenditure on health care per capita (USD, 2008–2012) <sup>b</sup>	123
Government expenditure on health as a percentage of total expenditure on health (2010) <sup>c</sup>	61
Expenditure on pharmaceuticals as a percentage of total expenditure on health (2000) <sup>d</sup>	20.3
Total expenditure on pharmaceuticals per capita at average exchange rate in USD (2000) <sup>d</sup>	5
Public expenditure on pharmaceuticals per capita at average exchange rate in USD (2000) <sup>d</sup>	1
Financing mechanisms for pharmaceuticals	Government, out-of-pocket expenditure, donors; percentages not available
Number of registered medicines	No product registration to date
Health workforce per 10,000 population (2005–2012) <sup>c</sup>	1.7 physicians; 16.6 nurses and midwifery personnel
<b>Medicine policy</b>	
Existence of national medicine policy	National Pharmaceutical Policy, 2010
Legal provision for medicine legislation	Draft Medicine Law (pending approval as of October 2012)
<b>Pharmaceutical industry</b>	
Domestic pharmaceutical manufacturing plants	None operational (as of October 2012; two in the process of setting up operations, according to DNME)
Pharmaceutical market size	n.a.
Local manufacturing capacity	n.a.
<b>Pharmaceutical personnel</b>	
Number of pharmacists (2009) <sup>e</sup>	127
Number of pharmacy technicians and assistants (2009) <sup>e</sup>	786
Number of newly registered pharmacists in last year (2009) <sup>e</sup>	10
Professional pharmacy association <sup>f</sup>	No national-level association; one provincial-level association in Huambo Province

*Note:* n.a. = not applicable.

a. World Bank, Data by Country, 2011, <http://data.worldbank.org/country/angola>.

b. World Bank, Data, Health expenditure per capita (current US\$), 2013, <http://data.worldbank.org/indicator/SH.XPD.PCAP/countries>

c. World Health Organization (WHO). 2103. *World Health Statistics 2013: Part III Global Health Indicators*. Geneva: WHO. [http://www.who.int/gho/publications/world\\_health\\_statistics/EN\\_WHS2013\\_Part3.pdf](http://www.who.int/gho/publications/world_health_statistics/EN_WHS2013_Part3.pdf).

d. WHO. 2004. *The World Medicines Situation*. Geneva: WHO.

e. WHO and SADC. 2009. "Country Data Profile on the Pharmaceutical Situation in the Southern African Development Community (SADC): Angola." <http://www.who.int/medicines/areas/coordination/Angolaweb.pdf>.

f. Connor, Catherine, Denise Averbug, and Maria Miralles. July 2010. *Angola Health System Assessment 2010*. Bethesda, MD: Health Systems 20/20, Abt Associates Inc.

## METHODOLOGY

An assessment of the current regulatory system in Angola and the capacity of the DNME was conducted from October to November 2012 by a USAID/SIAPS Angola technical team. The SIAPS team used the RSAT,<sup>13</sup> a baseline assessment tool developed by the SPS Program, to examine the status of the national medicines regulatory systems and the capacity of the national regulatory authority to effectively ensure the safety, effectiveness, and quality of medicines. The RSAT was developed through the adaption of existing assessment tools, including WHO tools (Guide for Data Collection to Assess Drug Regulatory Performance, Data Collection for Review of National Regulatory Systems, and Building Capacity through the Review of National Regulatory Systems); USP/DQI Rapid Assessment of Quality Assurance and Quality Control of Medicines; and the SPS Indicator-Based Pharmacovigilance Assessment Tool (IPAT). The RSAT consists of adapted assessment questions from these tools as well as additional questions to address issues of good governance and accountability in the regulatory system. It involves a review of key documents and use of structured questions to examine the primary regulatory functions as well as overarching areas related to governance and management. Findings generated from the RSAT are intended to facilitate the identification of weaknesses, gaps, strengths, and opportunities for strengthening national regulatory systems and capacities, which in turn can be used to develop options and key recommendations.

The Angola RSAT assessment covered the main components of the regulatory system, including the primary functions (product registration, licensing, inspection, quality control, and pharmacovigilance) as well as medicine legislation, organizational structure and systems, and governance. The specific objectives of the assessment were as follows—

- To identify strengths, weaknesses, gaps, and opportunities in the regulatory system
- To make recommendations for strengthening the system
- To assist partners in defining and reaching consensus on regulatory system strengthening priorities based on evidence
- To provide evidence that the DNME can use to advocate for the additional technical support and funding it needs to improve the regulatory system in Angola
- To create a baseline for measuring the system's performance and progress over time

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<sup>13</sup> Strengthening Pharmaceutical Systems (SPS) Program. Forthcoming. *Regulatory Systems Assessment Tool*. Arlington, VA: Management Sciences for Health.

## RESULTS AND FINDINGS

The DNME has a clear vision of the comprehensive and functional regulatory system it wants to develop and implement in Angola and a strong awareness of the current gaps in the system, which must be addressed to achieve its vision. A number of key steps have already been taken toward the achievement of the DNME's regulatory system goals, including adoption of a well-defined and comprehensive NPP in 2010, clear and documented plans (such as “The Health Development Plan—Pharmaceutical Development Program, May 2012” [Plano de Desenvolvimento Sanitário – Programa do Desenvolvimento Farmaceutico de Maio 2012]), and a proposal under discussion to transform the DNME into the National Institute of Medicine and Health Product Regulation (Instituto Nacional de Regulação Farmaceutica e de Produtos de Saúde). In addition, the DNME is in the process of improving and expanding the scope of its regulatory functions through the rollout of product registration, starting with the prequalification of suppliers (importers and wholesalers) and the creation of a national quality control laboratory for product testing. Nevertheless, substantial deficiencies in key areas of the current regulatory system exist and need to be addressed. The following is a summary of the deficiencies in the overarching areas of governance and operational or administrative capacity and by function (registration, licensing, inspection, pharmacovigilance, quality control, and import/export control).

### **Regulatory Framework and Management Structure of the Regulatory System**

#### ***Legal Framework***

Angola has a National Health Policy that covers pharmaceuticals as well as a comprehensive National Pharmaceutical Policy, both adopted in 2010. The NPP covers the roles and responsibilities of the different actors, supervision of pharmaceutical activities, registration and selection of pharmaceutical products, supply of medicines and medical products, national manufacturing of medicines, quality assurance of pharmaceutical products, rational use of medicines, economic strategies for ensuring the availability and accessibility of medicines, training and development of human resources, traditional medicines, scientific research (clinical trials), and control of policy implementation. Angola does not have a current Pharmaceutical Law. A draft law has been developed but has not yet been approved.

Although Angola has some regulations in place for pharmaceutical products, services, and industry, which apply across the public and private sectors, numerous regulations are still needed to solidify the legal mandate for a comprehensive regulatory system (table 2). The DNME has already identified the need for regulations for medical devices, traditional medicines, laboratory reagents, pharmacovigilance, the quality assurance system, advertising and promotion, labeling, and cosmetics and personal hygiene products.

**Table 2. Policies, Laws, and Regulations Governing the Regulatory System**

<b>Laws and legislation</b>	<b>Description</b>
National Pharmaceutical Policy	Adopted in 2010 to guide the pharmaceutical sector
National Health Policy	Adopted in 2010 to guide the health sector
Regulation of pharmaceutical activities	Adopted in 2010 with the NPP
Law n° 20/10, 7 September	Outlines quality considerations for procurement
Law n° 01/07, 14 May (Law of Commercial Activities)	Addresses licensing of commercial pharmaceutical activities
Presidential Decrees 287/10, 288/10, and 289/10, 30 November	Regulation of commercial activity (especially 289/10)
Presidential Decree 34/11, 14 February	Organizational framework for MINSA as a whole, including DNME specifically
<b>Laws anticipated (in process)</b>	
Pharmaceutical Law	Draft being reviewed for approval
Decree on medical devices	
Decree on traditional remedies	
Decree on reagents	
Law/decree on Pharmacovigilance	Reportedly submitted two years ago, but still not approved
Law/decree on quality assurance system	
Law/decree on advertising and promotion of pharmaceutical products	
Law/decree on labeling and packaging	
Law/decree on cosmetics and personal hygiene products	

Beyond the articles put forth in the NPP, legislation and regulations related to national manufacturing and good manufacturing practices do not yet exist to guide and ensure the quality of national manufacturing operations currently in development.

### **Structure**

The DNME currently operates as a national directorate within MINSA. However, one of the objectives in the Health Development Plan's Program for Pharmaceutical Development is to transform the DNME into an autonomous National Institute for the Regulation of Pharmaceuticals and Health Products by 2015, to serve as the national regulatory authority. Approval for the creation of a new autonomous regulatory authority has not yet been officially granted.

Under the current structure, the DNME is made up of three national departments—National Department of Medicines and Health Products, National Department of Equipment and Diagnostics, and National Department of Pharmacovigilance and Traditional Remedies—and two technical support bodies for administration and regulation. The current DNME structure includes only one committee that contributes to the regulatory functions, the CTNM. It is generally recommended that regulatory bodies use a variety of committees to fulfill their mandate, not only to increase stakeholder representation and participation in regulatory decision

making but also to supplement their in-house staff and technical expertise with specialists who have relevant skills and knowledge. Figure 1 illustrates the proposed organogram for DNME.

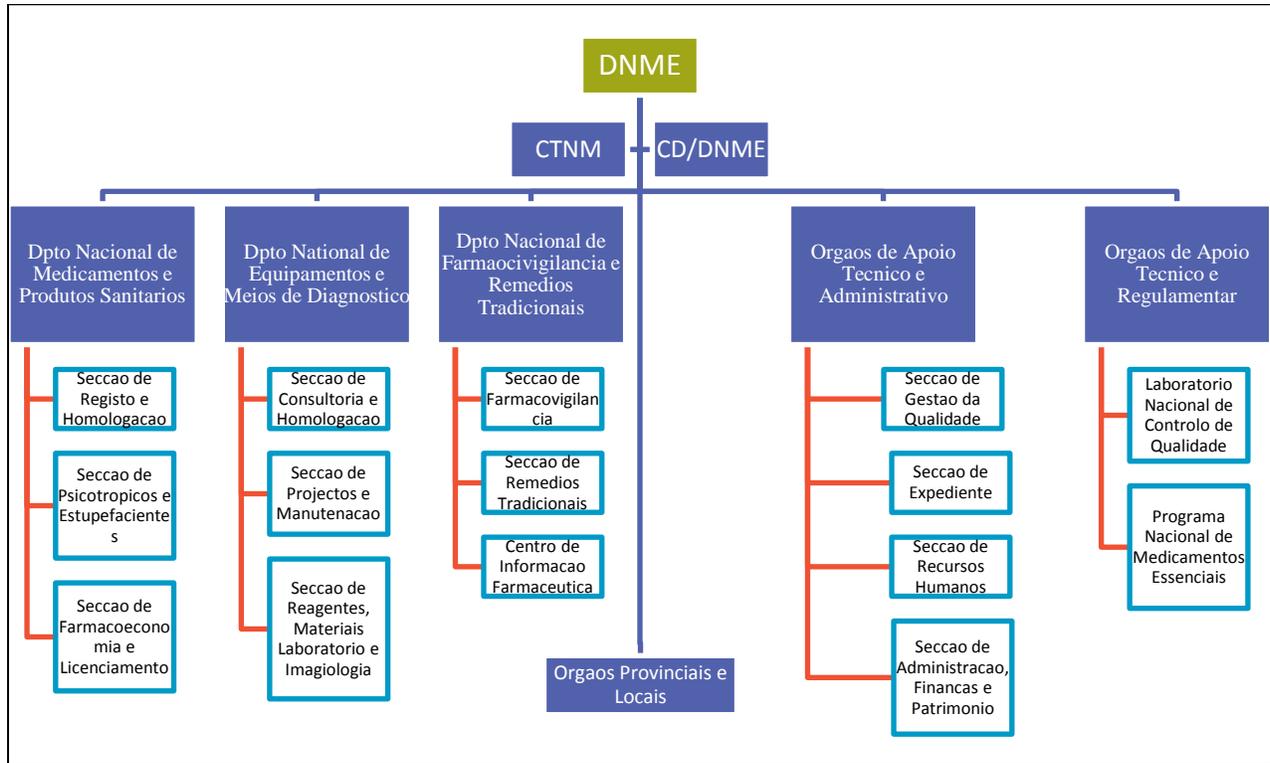


Figure 1. Proposed organogram for DNME

Although provincial and local organizations are included in the DNME’s organogram, very few of DNME’s regulatory activities are carried out by peripheral-level staff. The system is highly centralized, which places a heavy burden on the relatively small central-level staff, increases the cost of conducting activities in the provinces on account of travel expenses, and poses significant challenges to achieving full geographic coverage of the country by the regulatory system.

**Governance: Accountability and Transparency**

The DNME has a 10-year strategic plan outlined in the Health Development Plan’s Pharmaceutical Development Program document of May 2012. The plan focuses on five goals or objectives: (1) increase the availability of essential medicines; (2) increase the population’s financial access to medicines; (3) assure the quality of dispensed medicines; (4) promote the rational use of medicines; and (5) reinforce coordination in the pharmaceutical sector. For each of these goals, the DNME has defined strategies, activities, indicators, partners (responsible institutions), and implementation timelines.

Access to information on regulatory decisions and performance, as well as regulatory registers of licensed personnel and establishments, is a key component of transparency. Access to this type of information in Angola is limited because of the absence of appropriate platforms for

disseminating information and making it readily accessible to health professionals, patients and consumers, the public, and other stakeholders. The DNME does not have its own website or a webpage on the MINSA website. Furthermore, medicine bulletins are not published and distributed on a regular basis. Information is, however, available upon request from the DNME.

Implementing a monitoring and evaluation system is one of the primary and most effective ways a regulatory authority can demonstrate and improve its accountability to its stakeholders, including the government and the public. Although the DNME produces regular reports on its activities, most notably annual reports, it does not consistently report on a core set of performance indicators that cover the full scope of its mandated functions. Inadequate information systems across all of its functions pose a significant challenge to the DNME's capacity to implement an effective monitoring and evaluation system and to report on its performance.

## **Regulatory Functions**

### ***Registration***

Responsibility for pharmaceutical product registration falls under DNME's National Department of Medicine and Health Products, specifically the Registration Section. Although the NPP requires pharmaceutical products to be registered by the DNME before they are allowed into the country and distributed, pharmaceutical products are not currently being registered. Putting the registration requirement into practice depends on government approval, which has been pending for more than two years.

In preparation for the implementation of a product registration system, the DNME has developed the necessary instruments, including tools and guidelines; however, the Registration Unit has not developed a rollout plan that outlines how the system will be progressively and strategically introduced and scaled up in a manner that will not overwhelm the system and unit once the approval is granted and registration begins.

As acknowledged by the DNME, the current staff within the Registration Unit, a total of four members (two pharmacists, one pharmacy technician, and one administrative support), is insufficient, given the upcoming increase in workload and skill level required to perform the tasks.

An information system, including a database for registration of applications and approved products, has not been developed and adopted yet. The Registration Unit has been planning to implement and use the World Health Organization (WHO)'s model system for computer-assisted medicine registration, SIAMED; however, that system is no longer supported by WHO or recommended.

Registration fees have already been set, including a reduced fee for nationally manufactured products to encourage local industry once it is operational. Although 40 percent of the revenue generated through these fees will be used to finance some of the recurrent costs of the registration system, it will not be sufficient to cover the full cost of the registration process.

## ***Licensing***

Licensing is the responsibility of the Pharmacoeconomics and Licensing Section of the DNME's National Department of Medicines and Health Products. Licensing is required for private retail pharmacies, which are issued a license for three months (provisional, pending submission of all required documents), one year (all documents submitted), or two years (all documents submitted and requirements met). Currently, the licensing unit at the DNME licenses only pharmacies and does not issue any other types of licenses, such as licenses for pharmaceutical entities, personnel, imports and exports, or products, although import licenses are issued directly from the director of the DNME, and the registration unit is in the process of prequalifying importers and wholesalers in preparation for product registration.

Inspections are required as part of the licensing process for pharmaceutical outlets; however, insufficient resources (including staff and means of transportation) prevent the centralized Licensing Unit from consistently inspecting all premises applying for licenses within the legally mandated time frame of two months from the time of submission.

The information system for managing data on licenses is reportedly very basic and cannot easily monitor the status of licenses. License renewal is reportedly weak, in part because the Licensing Unit does not have reliable information or sufficient capacity to enforce it.

## ***Inspection***

Responsibility for the regular supervision and inspection of pharmacies, public and private, rests with the DIF at IGS, rather than the DNME. Inspectors at both the central and provincial levels are employed to conduct the mandated inspections using established tools, which define the areas to be evaluated. In the event that a violation is detected, the IGS has the authority to take administrative and judiciary action to enforce compliance.

The mechanisms for coordination and communication between the DIF at IGS and the other departments involved in the regulation of medicines at the DNME do not appear to be well defined or formalized, or as strong, effective, or efficient as they need to be to ensure adequate integration of the regulatory system's interdependent functions, timely information exchange, and rapid responses to urgent issues, particularly given the extensive scope and importance of the DIF's functions within the system.

As acknowledged by IGS, the DIF is understaffed with 33 total staff members at the central level, of whom only nine are pharmacists, two inspectors (pharmacists or pharmacy technicians) per province, and one inspector (pharmacist or pharmacy technician) per municipality.

Although plans are in place to start GMP inspections of manufacturers, all of which are outside the country at present, they are not currently conducted.

## ***Pharmacovigilance***

The Pharmacovigilance Section of the National Department of Pharmacovigilance and Traditional Remedies is responsible for the implementation of medicine safety monitoring

activities. Based on the limited scope of pharmacovigilance activities currently supported and implemented by the DNME's Department of Pharmacovigilance, the country does not yet have a comprehensive or effective national pharmacovigilance system in place, nor does it have a framework to guide the development of such a system.

The legislation that outlines the legal provisions and regulations for pharmacovigilance has been drafted but has not yet been approved, and the department is still in the process of drafting key guidance documents, such as guidelines and SOPs, for its activities

Reporting of ADRs appears to be low: no reports were received in 2011, and only six reports were received in 2012 (up to October). ADR report investigation and follow-up tends to be high for reports received from Luanda but very low for reports received from the provinces, because of limited human and financial resources.

Angola is an associate member of the WHO Programme for International Drug Monitoring; eligibility for full membership has been inhibited in part by the low number of ADR reports available to submit to meet the membership requirement (minimum 20 reports) as well as the lack of compatibility between the reporting formats of Angola and the WHO Uppsala Monitoring Centre (UMC). The head and key technical staff of the DNME Pharmacovigilance Unit have participated in regional and international meetings, conferences, and capacity-building trainings and related activities in pharmacovigilance (such as study visit to Kenya,<sup>14</sup> ANVISA, WHO UMC).

Currently, no active surveillance activities are being implemented to monitor medicine safety, particularly of medicines with high risk profiles.

The National Department for Pharmacovigilance and Traditional Remedies also houses the Center for Medicine Information, which is responsible for providing medicine information to providers and consumers. The dissemination of information on medicines, and particularly medicine safety issues, is limited: no bulletins have been issued since 2010 because of delays in approval, and the department does not have a website through which it can distribute information electronically. The Center for Medicine Information does have a library of books and other relevant resources, as well as computers for conducting electronic searches, which are most often used by medical and pharmacy students, according to Center staff.

### **Quality Control**

Angola does not currently have a national quality control laboratory for medicines, although plans are in place and space has been designated to develop a level I laboratory with the capacity to do basic testing specifically for medicines, which will be further supported by a national-level III laboratory with the capacity to do more extensive and definitive testing. At present, products

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<sup>14</sup> Goredema, W. 2011. *SPS Technical Assistance for Angola Ministry of Health Team Pharmacovigilance Study Tour to Kenya; November 25-December 2, 2011: Trip Report*. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

that need to be tested are sent to Infarmed or a private laboratory in Portugal or to ANVISA in Brazil

The DIF has ten mini-labs (five in Luanda), which are used to screen medicines for quality, primarily at the main ports and other points of entry. They are insufficient to cover all provinces in the country, some of which are remote and thus face significant challenges in reaching Luanda with samples.

### ***Price Control***

The Ministry of Finance sets medicine prices, and regulatory provisions are in place for setting maximum wholesale markup, maximum retail markup, and maximum retail prices (exit prices) of medicines. However, systems for monitoring and enforcing prices in the private sector are weak.

Plans have already been set forth in the pharmaceutical development plan to advocate for reducing taxes and duties on essential medicines, provide the resources needed to effectively monitor medicine prices, and strengthen enforcement.

### ***Contributing Factors***

Some of the contributing causes to the regulatory system's deficiencies and suboptimal performance, and potential threats to its improvement, appear to be—

- Delays in decision making and approval of plans and proposals at higher levels of the government
- A shortage of well-qualified pharmacists and specialists in the country, especially in the public sector, to meet the full range of professional pharmaceutical service needs (from regulation to patient care)
- The large geographic area, including numerous potential entry points for medicines, which the regulatory system must cover without adequate infrastructure to facilitate access
- The lack of a regulatory precedent or “culture” in the pharmaceutical sector, which may limit the cooperation and responsiveness of the different actors upon which the system's successful implementation depends

## OPTIONS AND RECOMMENDATIONS FOR STRENGTHENING THE REGULATORY SYSTEM IN ANGOLA

The regulatory system for medicines in Angola is not currently functioning at a level that can effectively assure the safety, effectiveness, and quality of medicines in circulation in the country; however, the DNME has clear and commendable vision and plans in place to strengthen its legal framework, structure, governance and regulatory functions. The findings of the assessment corroborate the planned activities already defined and outlined for the 10-year period, 2012–2021, in the Program for Pharmaceutical Development in the country’s Health Development Plan. In addition to those activities already set forth, the proposed options and recommendations presented in this section are based on this assessment’s findings. For each of the options and recommendations, a time frame for implementation—short, medium, or long term—has been proposed; however, regulatory system stakeholders are encouraged to use the matrix in Annex A to collectively define and develop an action plan, based on their priorities and the realities on the ground.

### Legal Framework

- *Develop a plan and a timeline for finalizing or developing the regulations currently absent from the legal framework for the regulatory system, based on priority for public health (i.e., impact), and identify technical assistance partners for each (as needed) so that the regulations can be efficiently developed and submitted. (Short to medium term)*
- *Develop legislation and regulations related to domestic manufacturing of pharmaceuticals in advance of the planned launch of national manufacturing operations to ensure the operators are aware of their legal requirements and responsibilities and the DNME has the legal authority and necessary guidance to effectively enforce quality and safety standards from the onset. The regulations and other legal guidance should not only protect public health through the application of stringent standards but also provide sufficient incentive for the national producers while still keeping costs down for consumers. (Short term)*

### Structure and Governance

- To the extent that consensus has not been reached on the necessity of creating an autonomous National Institute for the Regulation of Pharmaceuticals and Health Products: *Conduct an options analysis of the various regulatory structures under consideration (e.g., governmental, semi-autonomous, and autonomous) that compares their feasibility, in terms of financial, human resources, and capacity requirements, compared to the expected benefits for each and, most important, the specific regulatory needs of the country, current and future. The information used for the options analysis can then be developed into an operational plan for the selected option. (Short term)*
- *Conduct a costing analysis of current operations to identify opportunities for improved efficiencies at present funding levels and options for greater cost recovery, and to prioritize*

areas in need of additional funding, particularly relating to plans for scaling up operations for key functions. The results can also be used to assess the cost implications of becoming an autonomous regulatory authority, including opportunities for cost recovery and their sustainability, because an autonomous body will need to generate the necessary revenue to cover all of its expenses, including salaries and operational costs. (*Short term*)

- *Review the strategic plan, development plan, and annual work plan(s) to identify, define, and coordinate the DNME's technical assistance needs, so that current technical assistance partners (local and international) can be assigned to the identified areas and activities and additional partners and donors can be strategically enlisted to fill any gaps, as needed. Such an exercise will ensure that the DNME has the technical support it requires across all of its capacity-building and system-strengthening activities and help alleviate the burden on its limited staff, as well as improve coordination among its various partners. (Short term)*
- *Increase and strengthen the role of committees in technical reviews and decision making for functions throughout the regulatory system. Committees improve governance by increasing and diversifying participation in regulatory decisions and by involving specialists whose expertise may not be represented in the regulatory authority's staff. Most notably, the DNME should consider a committee for conducting the clinical evaluation of medicines for registration as well as a committee for evaluating ADR reports. (Short to medium term)*
- *Explore options for strategically decentralizing select regulatory functions or tasks to improve geographic coverage, reduce costs, alleviate the work burden on the central level, and build the capacity of peripheral-level pharmacy staff. If the DNME decentralizes additional functions to the provinces and districts, clear guidance documents will need to be developed, and effective training will need to be conducted to ensure the peripheral-level staff understand their responsibilities and have the capacity to perform their duties. New management structures may also be required, especially in more remote areas, to provide the necessary supervision. (Short to medium term)*
- *Develop a monitoring and evaluation plan that primarily defines a list of key performance indicators for the regulatory system (recommendations provided in Annex B) and includes guidance on data sources, collection, and quality as well as reporting requirements. The plan should lay the groundwork for a more robust monitoring and evaluation system as the DNME improves its information system(s). (Short to medium term)*
- *Improve the supply and demand for pharmaceutical information among health professionals, patients and consumers, and the general public through the creation and use of multiple platforms for communication and information dissemination, such as websites, bulletins, and MINSA's *Jornal da Saúde*. (Short to medium term)*

## **Relationship with Other Regulatory Authorities**

- *Maintain active communication, participation and coordination with the Southern African Development Community and the Southern African Regional Programme on Access to Medicines and Diagnostics to ensure that Angola's regulatory system strengthening efforts are consistent with regional goals and initiatives, particularly with respect to harmonization*

of product registration and GMP inspections, and to identify opportunities for information sharing and professional exchanges with member states. This includes involvement with the African Medicine Regulatory Harmonization. (*Ongoing*)

- *Establish agreements or memoranda of understanding with other regulatory authorities in the region, including regulatory authorities in neighboring countries, which are strategically important in establishing mechanisms for information sharing and coordination of efforts, particularly in relation to shared borders where medicines are or may be passing between the countries, either legally or illegally. Memoranda of understanding with more advanced regulatory authorities in the region are also important to pursue to create opportunities for capacity building and professional exchanges with countries that operate in environments similar to that of Angola and face similar challenges. (Short term; ongoing)*

## **Product Registration**

- *Develop a rollout plan for the registration of medicines, which includes prioritization criteria and fast-track procedures for certain products, along with realistic timelines and an appropriate scale-up of staffing (including training) that corresponds to the expansion of registration tasks. (Short term)*
- *Adopt the common technical document as the application format for product registration, in accordance with international standards. Adoption of the common technical document will further contribute to harmonization efforts.*
- *Identify an appropriate electronic information system for registration, and develop it before the Registration Unit begins accepting applications, so that it can be used from the outset, thereby avoiding a substantial backlog of information to be entered into the system. PharmaDex, an electronic information system developed by SPS and currently supported by SIAPS, which is in use in other countries, such as Namibia, is one system to consider, particularly because it can be rolled out to include additional modules for other areas of the regulatory system. (Short to medium term)*

## **Licensing**

- *Increase the human and financial resources available for carrying out inspections as part of the licensing process within the requisite time frame, including the decentralization of some tasks to provincial or municipal staff to minimize the unnecessary travel burden and associated costs of central-level staff. (Short to medium term)*
- *Identify and implement a more sophisticated information system for licensing, which facilitates monitoring of license expiries and renewals. An improved information system will allow the DNME to maintain a more accurate and up-to-date list of licensed retail pharmacies for the public as well as to identify establishments that have not renewed their licenses for the purposes of enforcement. (Short to medium term)*

- *Advocate for and support the DNME to become the sole provider of the importation licenses and visas for all imported medicines and other pharmaceutical products to ensure that all medicines are imported from a known and reputable source. This will be especially important once the peripheral levels of MINSA begin procuring medicines as part of a planned decentralization effort. (Short term)*

## **Inspection**

- *Assess the efficiency and effectiveness of established mechanisms for coordination and communication between the IGS and the DNME, specifically between DIF and the departments within DNME that are carrying out other essential regulatory functions, to identify weaknesses and opportunities for improving the flow of information and directives. (Short term)*
- *Develop the capacity of the DNME and the IGS to guarantee the quality of national manufacturing of medicines through GMP inspections in preparation for the introduction of manufacturing operations in Angola, including ensuring the legal mandate, developing guidelines and tools, and training inspectors. (Short to medium term)*
- *Explore opportunities to share GMP inspection information on international manufacturers from other regulatory authorities as a more cost-effective alternative way to ensure that only products from trusted sources are allowed to enter in Angola.*

## **Quality Control of Medicines**

- *Conduct a study of the quality of medicines in the country with the aim of better understanding the scale and nature of the problem, so that an evidence- and risk-based strategy can be developed and implemented and a baseline can be defined for ongoing monitoring of quality assurance and quality control efforts. (Medium term)*
- *Develop a plan for medicine quality monitoring that incorporates the use of mini-labs and uses an appropriate risk-based sampling strategy. A medicine quality monitoring program can help maximize the benefits of mini-lab testing in the overall quality assurance and quality control system, particularly in a resource-constrained setting, by making it more systematic and strategic. (Medium term)*
- *Enlist the technical support of an appropriate specialized technical partner to assist with the physical design and setup of the national medicine quality control laboratory, including the installation of equipment, the training of new laboratory technicians in basic tests and good laboratory practices, and the development of essential guidelines and procedures. The United States Pharmacopeia's Promoting Quality of Medicines Program, funded by USAID, has successfully provided similar support to national drug quality control laboratories in the region. (Short term; ongoing)*

## Pharmacovigilance

- *Develop and adopt a framework for a comprehensive National Pharmacovigilance System*, which illustrates the different components (existing and to be developed), identifies the partners and their functions, and can serve as a guide for planning pharmacovigilance activities and strategies according to a systems approach. Develop and disseminate any needed system tools, including SOPs, reporting forms, job aids, and appropriate information dissemination tools; develop and conduct appropriate interventions to enhance the capacity of health staff. (*Medium term*)
- *Develop and implement a customized, evidence-based, locally appropriate and feasible option for pharmacovigilance surveillance.* (*Medium term*)
- *Continue strengthening voluntary notification of ADRs and suspected low-quality products—*including follow-up investigations, the decision-making process, and the implementation of corrective actions—by consolidating and finalizing the tools and guidance documents, institutionalizing pharmacovigilance capacity-building trainings and related activities for health professionals (both pre- and in-service), and decentralizing some functions (namely, report follow-up, to peripheral level staff or Drug and Therapeutics Committees. As part of this effort, the Pharmacovigilance Department should ensure the compatibility of its reporting format and pursue full membership in the WHO Programme for International Drug Monitoring. (*Short term; ongoing*)
- *Explore opportunities and potential mechanisms for the active surveillance of medicine safety issues*, particularly for medicines with a high risk profile. Priority health programs, such as the National Tuberculosis Program or the immunization program, may offer good entry points for active surveillance. Partnerships with academic institutions can also be pursued. (*Medium term*)
- As recommended elsewhere<sup>15</sup>—
  - Promote collaboration among MINSA disease programs to strengthen and implement one national pharmacovigilance system, instead of vertical, disease-specific systems.
  - Promote collaboration with international organizations such as the WHO UMC on reporting and information exchange.
  - Ensure adequate resources are allocated to pharmacovigilance activities at each level of the national pharmacovigilance system; continuously advocate and create awareness to inform, guide, and help policy makers understand the importance and need to invest in pharmacovigilance program activities.
  - Promote ongoing dissemination of feedback on outcomes of pharmacovigilance surveillance activities from higher to lower levels of the national pharmacovigilance system.

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<sup>15</sup> Goredema, W. 2011. *SPS Technical Assistance for Angola Ministry of Health Team Pharmacovigilance Study Tour to Kenya; November 25–December 2, 2011: Trip Report*. Submitted to the US Agency for International Development by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

## **Financing**

- *Analyze the financial sustainability of the proposed autonomous medicine regulatory authority and its proposed functions and services, compared to the current and proposed fees for medicine regulatory services and other sources of funding and revenue, to improve the transition of this new agency to financial autonomy. (Medium term)*

## CONCLUSION

The DNME has a clear vision for strengthening its capacity to be an effective and fully functional national regulatory authority. Many of the essential structural components of a functional regulatory system are in place, in progress, or planned, and well-defined strategic and work plans have been developed and documented to guide strengthening of the DNME's capacity to perform its technical functions. Although opportunities still exist to improve upon the plans, the main challenge appears to be the operationalization of the structures, plans, and tools that have already been developed but not implemented because of a combination of factors related primarily to funding, technical support, and political priority.

Advocacy and sensitization efforts targeting stakeholders, ranging from high-ranking government officials to pharmaceutical industry representatives to academia and other stakeholders in the pharmaceutical and health sectors, including patients and consumers, are needed to generate support for and speed up some of the changes and reforms that are being either proposed or implemented. The DNME will undoubtedly require additional technical assistance and funding to ensure that the changes and improvements do not overwhelm the system and are implemented effectively. Continued active communication, participation, and coordination with regional and international medicine regulatory authorities and initiatives is critical for knowledge exchange and sharing of experiences, lessons learned, and solutions, to ensure Angola's regulatory system strengthening efforts are consistent with regional and international goals and initiatives. Ongoing reciprocal visits and participation in international medicine regulatory activities could contribute toward achieving this goal.

## ANNEX A. MATRIX FOR DEVELOPING THE ACTION PLAN

Area to be addressed	Short term (under 1 year)	Medium term (1–3 years)	Long term (over 3 years)
<b>Regulatory framework and management structure</b>			
Regulatory framework (including legislation and regulations)			
Harmonization			
Organizational structure			
Human resources			
Quality Management System			
Governance (transparency and accountability)			
Technical capacity			
Automation and information technology			
<b>Regulatory functions</b>			
Risk-based regulatory strategy			
Administration and capacity for registration			
Good Regulatory Practices guidelines			
Regulatory registers			
Fees charged for regulatory services			
Pricing			
Inspections			
Licensing of manufacturers, importers, wholesalers, and retailers			
Import and export control			
Quality control/WHO GMP standards			
Advancement of the pharmaceutical industry			
Rational use			
Control of promotion and advertisement			
Pharmacovigilance and postmarketing surveillance			
Clinical trials			

## ANNEX B. PERFORMANCE INDICATORS (EXAMPLES)

Category	Indicators
Management	Number of audits/management review/self-assessments carried out in the last year (per quality manual)
	Number of filled positions of total approved positions
	Number of staff who participated in regulatory affairs training in the last year
Enforcement	Number of violations against which administrative measures have been taken in the last year, of the total number of violations registered
	Number of violations against which legal sanctions have been applied by the judiciary in the last year, of the total number of violations submitted to court
Inspection	Number of planned pharmaceutical establishment inspections conducted, of the total number of planned inspections— <ul style="list-style-type: none"> <li>- Manufacturers</li> <li>- Retail pharmacies</li> <li>- Wholesalers</li> </ul>
	Number of clinical trial inspections carried out in the last year, of total clinical trials registered in country
Licensing	Number of pharmaceutical establishments (manufacturers, wholesalers, importers and exporters, retail pharmacies, etc.) licensed in the last year, of the total number of pharmaceutical businesses
	Number of renewal certificates issued for pharmaceutical establishments (manufacturers, wholesalers, importers and exporters, retail pharmacies, etc.)
Quality surveillance	Number of samples collected, of the total number of samples planned to be collected
	Number of products tested, of the total number of products submitted or collected
	Number of products that failed quality tests, of the total number of products tested

*Results and Findings*

Registration	Number of registered pharmaceutical products—
	<ul style="list-style-type: none"> <li>- New applications for registration of products containing new active pharmaceutical ingredients</li> <li>- New applications for registration of generic or well-established multisource products</li> <li>- New applications for medical devices</li> <li>- New applications for biologics and vaccines</li> <li>- New applications for registration by fast-track procedure</li> <li>- Applications for variation of data</li> <li>- Applications for renewal</li> <li>- Applications for export certificate</li> <li>- Other (specify):</li> </ul>
	Average time taken to evaluate and register—
	<ul style="list-style-type: none"> <li>- Generic products</li> <li>- Products containing a new active pharmaceutical ingredient</li> <li>- Fast-track products</li> </ul>
	Percent of all medicines in the essential medicines list registered
	Percent of all medicines in the standard treatment guidelines registered
	Percent of all products procured from CECOMA (Central de Compras de Medicamentos de Angola) that are registered
Average number of products registered for top 100 conditions in the country	
Average percent price reduction in price of products for the top 100 conditions in the country	
Pharmacovigilance	Number of risk mitigation recommendations that were informed by pharmacovigilance data and activities
	Number of medicine safety actions (other than mere ADR reporting) taken to inform clinical management, guideline revisions, regulatory decisions, or health worker or patient education
Medicine information	Number of essential therapeutics information services provided to support training of health care providers, treatment guidelines revision, and regulatory decisions
	Number of advertisements or promotions found to be in violation of the law, of the total number of promotions and advertisements approved (indicate year)
	Number of labels or inserts found to be inconsistent with what was approved during registration, of the total number of labels and inserts assessed (indicate year)