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MINISTRY OF PUBLIC HEALTH
GENERAL DIRECTORATE OF PHARMACEUTICAL AFFAIRS

ASSESSMENT REPORT ON REGULATORY FRAMEWORK
AND STRUCTURE FOR MEDICINES AND FOOD
IN AFGHANISTAN

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About SPS

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

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ACRONYMS AND ABBREVIATIONS

AfFDA	Afghanistan Food and Drug Administration (AfFDA)
ANSA	Afghanistan National Standards Agency
ASMED	Afghanistan Small and Medium Enterprise Development Project
COMPRI-A	Communication for Behavior Change: Expanding Access to Private Sector Health Products and Services in Afghanistan
CPDS	Coordinated Procurement Distribution System
DAI	Development Alternatives, Inc.
DEWS	Disease Early Warning System
EPI	Expanded Programme on Immunization
FAO	Food and Agriculture Organization
GDPA	General Directorate of Pharmaceutical Affairs
GIRoA	Government of the Islamic Republic of Afghanistan
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis Critical Control Point
HPIC	Health Partners International of Canada
MAIL	Ministry of Agriculture, Irrigation and Livestock
MoCI	Ministry of Commerce and Industry
MoF	Ministry of Finance
MoJ	Ministry of Justice
MoPH	Ministry of Public Health
MSH	Management Sciences for Health
NDTC	National Drug and Therapeutics Committee
NMFB	National Medicine and Food Board
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
SPS	Strengthening Pharmaceutical Systems Program
TAFA	Trade and Accession Facilitation for Afghanistan
USAID	U. S. Agency for International Development
WHO	World Health Organization

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COMMENTARY

In the last three decades the food and medicine management system of Afghanistan has suffered heavy blows similar that of other sectors. The food production and processing facilities, along with its control and management system, has weakened as a result of which Afghanistan turned into an importing country for processed food and medicine.

Lack of strong food and medicine management and regulatory system in the country has paved the way for easy selling and buying of sub-standard and unsafe processed food and medicine. This has led to prolonging of treatment and emergence of numerous diseases and at some point it has even led to death of many of our citizens.

To implement an effective plan which can be compatible with the present situation, it is, firstly, important to know what is the current state of medicine and food in the country and what opportunities and challenges does it pose to field. In addition, to design public health policies and strategies in the field, this particular information can be used as a guide and reference.

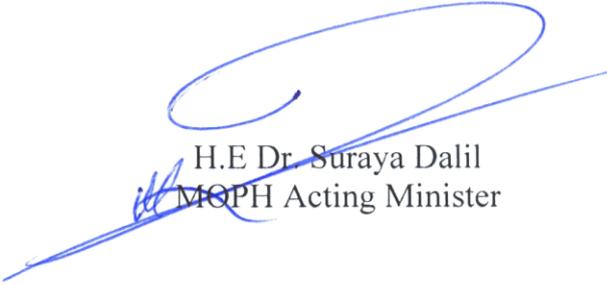
Therefore, General Department of Pharmaceutical Affairs (GDPA) of Ministry of Public Health (MOPH) which also acts as the Deputy Chair Person for National Medicine and Food Board (NMFB), conducted an initial assessment at the central level in April/May of 2010 with the financial and technical support of SPS/MSH. The interpretation and analysis which is presented in the document under the name of "Assessment Report on Regulatory Framework Structure for Medicines Food in Afghanistan" comprises valuable and in-depth information about medicine and food sectors.

Information obtained from the Assessment Report indicates that "preparing Essential Drugs List (EDL) and Licensed Drugs List (LDL) is the positive achievement made in pharmaceutical sector. Lack of food regulation and law, insufficient degree of law execution, fragmented structure and little communication, lack of clear definitions and descriptions of the roles and responsibilities of the various departments involved in medicine control, which has resulted in duplication of efforts and authority, vague system of accountability and responsiveness, recording, processing of and insufficient storage of documents, insufficient tools (Standard Procedures etc.), unsatisfactory performance in the areas of adverse drug reaction (ADR) and control of drug promotion and lack of clear approach with regard to involvement of various Ministries in the area of Food and Medicine law and regulation." are all the plausible reasons that have led to the entry of substandard and unsafe [food and medicine] products in the country. It, therefore, demands for establishment of a comprehensive plan to regulate food and medicine at the national level.

Based on the recommended short term, long term and mid-term objectives and options of this report, the Ministry of Public Health (MOPH) is committed to strengthening the regulatory affairs of food and medicine regulation at the national level through providing support to strengthen the NFMB's capacity, adding secretariat to the NFMB Board, revising food and medicine policy, legislations and regulations implementing them.

I hope that various Departments of Ministry of Public Health (MOPH), other partner Ministries, government agencies, donors and NGOs synchronize their activities in delivery of better health services with the help of facts and findings of this Assessment Report and carry out their programs on the food and medicine regulatory affairs based on this report.

The Ministry of Public Health acknowledges the contribution of all stakeholders involved in this assessment and is also grateful to the technical and financial support of Management Sciences for Health's (MSH) Strengthening Pharmaceutical Systems (SPS) Program which operates with the financial assistance of U.S. Agency for International Development (USAID). I am looking forward to seeing more such programs implemented by this particular project.

A handwritten signature in blue ink, consisting of a large, stylized loop at the top and a long, sweeping underline that extends to the left and then curves back under the text below.

H.E Dr. Suraya Dalil
MOPH Acting Minister

EXECUTIVE SUMMARY

In October 2009, the Ministry of Public Health (MoPH) of Afghanistan requested that the Strengthening Pharmaceutical Systems (SPS) Program explore options for establishing a comprehensive regulatory framework for food products and medicines in Afghanistan.

From April 18 to May 7, 2010, the SPS consultants visited Kabul, Afghanistan to conduct an initial assessment to understand the existing regulatory structures and functions performed by governmental and nongovernment organizations (NGOs) involved in pharmaceutical and food products. The assessment is based on interviews and meetings with selected stakeholders, including officials at the MoPH; Afghanistan National Standards Agency (ANSA); Kabul University Faculty of Agriculture and Pharmacy; Ministry of Agriculture, Irrigation, and Livestock (MAIL); Food and Agriculture Organization (FAO) of the United Nations; World Health Organization (WHO); U.S. Agency for International Development (USAID); the Communication for Behavior Change: Expanding Access to Private Sector Health Products and Services in Afghanistan (COMPRI-A Project); Health Partners International of Canada (HPIC); Ministry of Commerce and Industries (MoCI); Ministry of Justice (MoJ); and Guzarga Dairy Products, and the Pharmaceutical Enterprise Department. The consultants also compiled and reviewed available reports and journal publications relevant to the country's food and pharmaceutical regulatory structure.

According to WHO's proposed drug regulation framework,¹ a drug regulatory authority shall cover four dimensions: (1) administrative components, (2) regulatory functions, (3) technical elements, and (4) level of regulation. For this assessment, the team addressed the following components within each dimension—

- Administrative components—policy, legislation and regulations, organizational structures, and financial resources
- Regulatory functions— inspection
- Technical elements—existence and type of standards, norms, guidelines, specifications, and procedures
- Level of regulation

The consultants discussed the key findings and recommended priority intervention areas with the two key stakeholders, the MoPH and the USAID.

The assessment findings suggest three overarching priority interventions to establish a functional regulatory body to address the quality of food and medicine products in the country. These priorities are to—

- Review and update, as necessary, legislation for medicines and for processed and retail food products

¹ WHO. 2002. *Effective drug regulation A multicountry study*. Geneva: WHO.

- Strengthen quality assurance systems for medicines and processed and retail food products in the industries, government, and academia
- Strengthen the capacity of the National Medicine and Food Board (NMFB) to effectively regulate processed and retail food products and medicine products

To achieve these priorities based on the country’s existing resources and infrastructure, the SPS Program identified the following options for the MoPH to carry out—

Option 1: Strengthen the capacity of the NMFB

Option 2: Help strengthen the existing infrastructure and leverage resources that can be shared in medicine and food product regulatory activities

Option 3: Help establish an independent Afghanistan Food and Drug Administration (AfFDA)

This report discusses the overall and specific objectives, intervention strategies, expected outcomes, and sustainability considerations for each option. Strengthening the capacity of the NMFB can be considered a short-term option; interventions can be initiated and implemented within a one-year period with specific measurable outcomes available in one to three years. However, this short-term approach can be expanded to support a more long-term strategy. Option 2 offers interventions that can be initiated and implemented within one year, resulting in concrete results in five years, given committed political will and available resources. Option 3, establishing an independent AfFDA, is a long-term strategy considering the time it would take to reach consensus among stakeholders. Interventions proposed under this option would be initiated and implemented in one to three years, with measurable outcomes achievable beyond five years. Each option can be independent of the others, with discrete interventions developed and implemented over time.

Alternatively, by strengthening and building the NMFB’s capacity, along with improving the quality and safety standards of medicines and food products and reviewing and updating legislations, the NMFB can undergo functional transfers and evolve into an AfFDA-type structure, that combines all medicines and food products’ regulatory activities under one agency/authority over the long term. Under this option, the NMFB would become an advisory role to the AfFDA.

These proposed options are consistent with the Afghanistan Health and Nutrition Strategy of the Afghanistan National Development Strategy and build on existing structures and resources, strengthen local capacity, complement ongoing initiatives without duplication, and leverage existing and potential resources.

INTRODUCTION

Since 2001, the Government of the Islamic Republic of Afghanistan (GIROA), along with a great number of donors, nongovernmental organizations (NGOs), and international organizations, has been addressing the needs of its population, initially in a relief manner and lately in a developmental manner. In 2002, the U. S. Agency for International Development (USAID) began providing pharmaceutical management technical assistance to the Ministry of Public Health (MoPH). In 2008, the Strengthening Pharmaceutical Systems (SPS) Program implemented by Management Sciences for Health (MSH), established a country office in Kabul and has since been working closely with the MoPH at the central and provincial levels to improve the use of medicines and the quality of pharmaceutical services in Afghanistan.

The General Directorate of Pharmaceutical Affairs (GDPA), of the MoPH, has the primary mission to provide useful and equitable pharmaceutical services for all people in Afghanistan in both the public and private sectors. In addition, the National Food and Medicines Board (NFMB), established in October 2009, is a stand-alone, independent board with jurisdiction over the quality of food and medicines. The NFMB is not located within the GDPA or the MoPH, but does report directly to the Minister of Public Health. The NFMB is a committee comprised of individuals from several institutions, including the relevant ministries, international and national organizations, associations, the private sector, and academia.

Over the past year, the Government of the Islamic Republic of Afghanistan (GIROA), has asked that SPS help establish a regulatory authority to oversee both medicines and processed and retail food products. The current system, comprised of several different government entities, has some regulatory functions, but there is no permanent structure that can effectively regulate food. The government would like to establish a full-fledged agency with all the functions, structures, human resources, and departments dedicated to regulating medicines and processed and retail food products.

SPS arranged for a four-member team to visit Kabul from April 18 to May 7, 2010. The team's mandate was to assess the existing regulatory mechanisms and systems for medicines and processed and retail food products and to propose options and approaches for the development of a regulatory authority framework for both food and medicinal products in Afghanistan. This report summarizes the findings related to food and medicinal products, and proposes approaches that use existing resources to strengthen current systems in the short term and identifies strategies to establish a comprehensive and sustainable regulatory system over the long term. The team's findings result from interviews with stakeholders in medicines and food regulations, inspections, education, and safety. (Annex 1 contains a list of the persons interviewed.) In addition, the team reviewed existing legislation, regulations, and earlier assessments.

ASSESSMENT GOALS AND OBJECTIVES

SPS conducted an initial assessment of the existing regulatory mechanisms and systems for food and medicinal products with the goal of proposing options and approaches for a well-developed regulatory framework. To this end, SPS—

- Mapped out the current roles and responsibilities of the stakeholders involved in the control of food and medicines and identified any gaps
- Assessed the adequacy of existing legislation and regulations to support basic food and medicines control functions
- Assessed the adequacy of existing technical and financial resources, suggested options to further strengthen those resources, and explored potential resources outside the MoPH
- Developed and proposed options for the organizational structure and staffing requirements needed to adequately control medicines and food products
- Reviewed the mandate, structure, and membership of the NFMB to determine if any short-term support could be provided, pending the establishment of a permanent regulatory structure
- Proposed a reasonable and realistic strategy to proceed with an option on which stakeholders agree

Specifically, in the realm of food products, the consultants—

- Assessed the existing legislation and regulations intended to prevent the health hazards and risks from food borne contamination
- Reviewed regulations and existing mechanisms involved in quality assurance (QA) of imported and in-country processed food products
- Consulted with key stakeholders to design a regulatory model to minimize risk and to enable the establishment and implementation of policies and procedures to regulate the quality of imported and locally produced food products
- Explored and identified existing technical resources inside and outside of the MoPH to assist with food product QA regulation, including testing, inspection, registration, distribution, and enforcement
- Recommended an appropriate set of activities and developmental priorities for the proposed regulatory structure, including defining the scope of product coverage

Specifically, in the realm of medicinal products, the consultants —

- Assessed the existing legislations, regulations and enforcement on the safe use of medicines, and QA regulations and mechanisms for imported, local and donated products
- Consulted with key stakeholders to design a regulatory model to minimize risk and to enable the establishment and implementation of policies and procedures to regulate the quality of imported and locally manufactured medicines and to ensure the proper use of medicine
- Explored and identified existing technical resources inside and outside of the MoPH to assist with pharmaceutical QA regulation, including testing, inspection, registration, distribution, and enforcement
- Recommended an appropriate set of activities and developmental priorities for the proposed regulatory structure; defined the scope of product coverage, including medicines, vaccines, dietary supplements, medical devices, and cosmetics

The assessment team interviewed 24 stakeholders related to food and medicine regulation (7 food-specific, 6 medicines-specific, and 11 related to both). In addition, the consultants compiled and reviewed relevant reports and journal publications for background information.

SUMMARY OF FINDINGS: CURRENT STATUS AND IDENTIFIED GAPS

According to the World Health Organization's (WHO) proposed drug regulation framework,² a drug regulatory authority should cover four dimensions: (1) administrative components, (2) regulatory functions, (3) technical elements, and (4) level of regulation.

For the purpose of this assessment, the team of consultants addressed select components within each of the four dimensions. Under the administrative components, they covered policy and the organizational structures related to legislation, regulations and financial resources. The team did not cover human resources or mechanisms for planning or monitoring and evaluation. The team's assessment of the regulatory function component included inspection and surveillance, but did not include licensing of persons, premises, and practices; product assessment and registration; quality control, control of drug promotion and advertising, or adverse drug reaction monitoring. Under technical elements, the team reviewed the relevant quality standards and then assessed the overarching level of regulation.

Administrative Components—Policy, Legislation, and Regulations

Current Status

Pharmaceuticals are regulated by two different branches of the MoPH. Medicine quality control falls under the jurisdiction of the MoPH's General Directorate of Technical Affairs; whereas, procurement for the Central Medical Store that supplies medicines to health facilities is part of the MoPH's General Directorate of Administrative Affairs.

The NFMB, an advisory board to the MoPH, is structured to oversee the technical and administrative issues related to pharmaceuticals and processed and retail food products, address issues on an as-needed basis, and make consensus recommendations to the Minister of Public Health. The NFMB meets every 15 days; its responsibilities include removing unsafe food from the market, updating and revising legislation and regulatory activities, and strengthening research and development of medicines and food products.

For processed and retail food products, Afghanistan does not have a law that describes food control activities and the responsible agencies and their terms of reference, nor do the respective ministries have specific legislation in place for regulating food.

A memorandum of understanding exists between the MoPH and the Ministry of Agriculture, Irrigation and Livestock (MAIL) that clearly defines the responsibilities for food safety control and regulation. Unprocessed and raw food is the responsibility of MAIL and the safety and regulation of processed and retail foods are the responsibility of the MoPH.

The MoPH has issued few regulations. For example, imported processed food and mineral water can only be sold upon release by the Food and Drug Quality Control Department. The MoPH requires that local food processing companies be examined by food safety inspectors, have QA systems in their production facilities, and send their products to the Food and Drug

² WHO. 2002. *Effective drug regulation A multicountry study*. Geneva: WHO.

Quality Control Department for quality control testing,³ but the Food and Drug Quality Control Department does not test for food safety.⁴

The Ministry of Commerce and Industries (MoCI) is responsible for issuing licenses to private food enterprises such as restaurants and grocery markets.

Identified Gaps

Even though a national drug policy and strategy exists, it does not contain current information, such as on the newly established National Drug and Therapeutics Committee (NDTC) or the Coordinated Procurement Distribution System (CPDS). Therefore, an update to the policy and strategy is required to reflect the changes. For legislation, clear definitions and descriptions of the roles and responsibilities of the various departments involved in medicine control is lacking, which has resulted in duplication of efforts and authority conflicts.

The NFMB was established to address the regulatory and communications gaps among various agencies related to medicines and processed and retail food products; however, it has been unable to adequately meet this objective in the absence of a comprehensive framework, terms of reference, or mandates. Nor does the NFMB have mechanisms to track, monitor, and follow through on recommendations.

No major laws or regulations exist related to the quality and safety of processed foods or food products sold at the retail level. As with medicines, a clear definition and description of the roles and responsibilities of the various departments involved in processed and retail food products is lacking resulting in duplication and jurisdictional conflicts.

The NFMB has oversight over some of the regulatory functions for processed and retail food products, but insufficient board member expertise on food regulations and a lack of accessibility to technical experts prevents it from appropriately addressing these regulatory issues. A few mechanisms exist in other ministries to control food products; however, there is no existing permanent structure that can effectively support all of the required functions for food control effectively.

Administrative Components—Financial Resources

Current Status

Funding for laboratory operations is based on an allocation from the Ministry of Finance (MoF) and is unrelated to the laboratory's activities. Companies pay the fees for quality control tests directly to the government treasury. The Food and Drug Quality Control Department has no mechanism to recover costs from any testing of imported and domestic food products.

³ Food quality: testing the food composition to determine whether the standards are being met.

⁴ Food safety: testing the potential health hazards from the food, such as presence of bacteria, heavy metals, or mycotoxins.

The Kabul University Faculty of Pharmacy tests medical devices and is compensated by the NFMB for this service; 40 percent of the payment is retained by the school, and 60 percent is returned to government treasury.

Gaps Identified

According to laboratory staff, the fixed budget allocation for medicines and food products does not sufficiently cover operational expenses, such as laboratory equipment, reagents, and maintenance. Consequently, service quality varies based on the availability of resources, which results in a compromised level of effort.

Regulatory Function—Inspection

Current Status of Pharmaceutical-Related Inspection

The Legislation Implementation Ensuring department of Technical Affairs of the MoPH inspects pharmacy establishments, including hospital and community pharmacies. The Kabul section of this department has 70 inspectors to cover all categories, including pharmacy establishments, manufacturers, importers, private hospitals, laboratories, and clinics. Twice per month, 10 groups of 5 inspectors each inspect pharmacies and collect suspect product samples. In addition, each of the 34 provinces has inspectors on staff.

There is no inspection training per se, instead, inspectors are trained on-the-job and rely on their past experiences. The routine inspections are guided by the standard checklist for the various establishments, such as clinics, restaurants, retail pharmacies, etc. The inspector communicates the findings to the relevant agency or department to follow through on the corrective actions.

The law requires the application of Good Manufacturing Practices (GMP) for manufacturing plants. Exact records on the number of routine GMP inspections carried out per year were not available; however, interview results indicated that about 12 or 13 plant inspections were performed each year. Inspectors do not use a checklist for GMP inspections, and there were no records of plants inspected because of complaints. No administrative or regulatory measures were taken against plants not compliant with GMP in the past three years.

The GDPA's Supervision and Monitoring Department handles inspection of domestic pharmaceutical manufacturers and import companies; imported medicines are inspected at the port of entry. Kabul has only two sample collectors, and every other province has only one collector.

A product batch is sampled by a customs officer and an accompanying GDPA inspector from the Sample Collection Unit. The sample is coded and sealed by customs and the Provincial Health Directorate and is sent to the GDPA by the importer. The GDPA forwards the coded sample to the FDQCL; medical devices are forwarded to the Faculty of Pharmacy at the Kabul University. The goods are then released by the customs department upon receipt of acceptable quality testing results; results are also sent to the GDPA and the Provincial Health Directorate. The total process takes between two to ten days, depending on the product and the number of samples in the shipment.

For surveillance of medicine, the Legislation Implementation Ensuring Department, in partnership with GDPA, conducts surveillance on retail pharmacies by checking for counterfeit and poor quality medicines. The Monitoring and Evaluation Department under the MoPH monitors private and public health facilities, although the exact role and function of this department government is not settled.

Current Status of Food-Related Inspection

For processed and retail food products, ministries and institutions that are involved in food control activities in Afghanistan include the MAIL, MoCI, MoPH, MoF/Customs Department, and the provincial health departments.

Applications to open a hotel or a restaurant must be submitted to the MoCI. For an applicant to obtain a hotel or restaurant license, the business's characteristics must be consistent with international norms and standards (not specified in the license application form), and all staff (local and foreign) must have health cards. The Directorate of Health in the MoPH is in charge of the medical check and the distribution of health cards to all personnel.

MAIL has laboratory facilities for testing raw products sold at the retail level such as meat, cereals, eggs, dairy products, and fertilizers and other agricultural materials. The tests are mainly microbiological. Although, the Department of Veterinary Medicines has the capacity to detect viral contamination in food products as well as zoonoses in animals, they do not have the human resources to carry out such testing. Wheat is visually inspected for physical properties only because there is no capacity to test for protein and gluten. MAIL inspectors take samples of some products and send them to be processed by the Faculty of Agriculture at Kabul University.

The Environmental Health Department in the MoPH is responsible for food safety inspections in markets, other food establishments, and butcher shops. The department has 14 food safety inspectors for Kabul. Food Safety Inspectors collect approximately 800 samples per year and submit them to the Food and Drug Quality Control Department for examination. Checklists are used for the inspections, and the lists are shared with establishments being set up for small-scale food production or catering. This department also issues health certificates to food workers that are valid for three to six months. In the provinces, the food inspection responsibility lies with the provincial health departments.

The Food and Drug Quality Control Laboratory tests food and water samples provided by the various MoPH departments. In 2009, the laboratory processed a total of 968 food samples and 597 water samples (mostly bottled water and only a few from the municipal water supply). The tests performed on food were for bacteria; pH; and nutrition, including protein, sugar, glucose, moisture, and total water. Water is tested for nitrate, sulfate, ammonia, chloride, conductivity, pH, hardness, and for bacterial presence.

The Food and Drug Quality Control Department staff members (19 pharmacists and 1 technician) conduct both food and drug analyses. Because the budget is limited, it is difficult to hire, retain, and train highly qualified personnel (we did not review staff competencies). The laboratory space is less than adequate and poorly equipped. Important instruments, such as two new high-performance liquid chromatography units were donated by the United Nations Children's Fund; at the time of our interview on April 25, 2010, both remained in their original packaging because no staff was trained on operating the instruments.

Afghanistan has a Disease Early Warning System (DEWS), which was established in the MoPH's Afghan Public Health Institute in December 2006, for responding to food-borne illness and zoonoses outbreaks. The program (in 34 provinces with focal points at 198 sentinel sites) is staffed with emergency/outbreak response teams for an integrated response to outbreak threats, including investigation, surveillance, and reporting.

Gaps Identified

The lack of standardized training for inspectors is a major gap. Because the training is not standardized, inspectors may have an incomplete or incorrect understanding of what constitutes a violation, as well as what is an appropriate fine or punishment. In the absence of standardized practices among inspectors, it becomes difficult for establishments to adhere to the guidelines/standards. Although manufacturers are required to follow the GMP guidelines/standards, in the absence of a GMP inspection checklist, inspections are haphazard, and manufacturers have difficulty knowing what to expect. As a result, the quality of their products may vary depending on how GMP is implemented and how strictly it is enforced.

In general, the chain of custody for medicine samples is too complex and the integrity of the samples cannot be ensured. With only two full-time staff in Kabul and one in each of six other provinces, it is clearly not possible to maintain control at all the points of entry, the consequence of which is illegal imports. In addition, with the capacity limitations of the Food and Drug Quality Control Department, the accuracy and reliability of the testing results are also questionable.

For surveillance of medicines, the country does not have any mechanism or system for monitoring the quality of medicines, adverse medicine reactions, or product recalls. Essentially, there is no organized and comprehensive surveillance program to monitor the market.

The inspection of food and food establishments is currently the responsibility of three separate ministries—MAIL, MoPH, and MoF, with little communication or coordination among them.

The activities of the Environmental Health Department in regard to food control are minimal and focused on imported foods. Little work is carried out on domestically produced foods, and inspection at the retail level is minimal. The present system of inspection and testing is complicated, inefficient, and prone to errors and failures. The chain of custody for food samples is circuitous, and the integrity of the samples cannot be preserved. For example, the Environmental Health Department took a sample from a consignment of imported biscuits at the Kabul Customs Office and sent it to Food and Drug Quality Control Department to test for sodium pyrophosphate. The sample failed and the Food and Drug Quality Control Department claimed the Environmental Health Department did not take the sample properly. The Food and Drug Quality Control Department dispatched their own staff to take a second sample which passed. As a result of this action, questions arose as to which department is responsible for taking product samples.

There is no routine market surveillance of food processing operations or the retail food supply. For food production facilities, no QA systems, such as a Hazard Analysis and Critical

Control Point (HACCP)⁵ were being implemented. Currently, the main emphasis of the few ongoing control activities seems to be on imported food items, which are being sampled only at points of entry and tested only for quality, not safety. The total exposure of the Afghan people to food-borne illnesses from domestic and imported foods (other than outbreak investigations) is currently unknown and should be monitored.

Technical Elements

Current Status

Because Afghanistan does not have a national pharmacopoeia, the Food and Drug Quality Control Department primarily uses the British Pharmacopoeia and the U. S. Pharmacopoeia as standards for testing medicines. It also recognizes and uses standards from the Japanese Pharmacopoeia, International Pharmacopoeia, European Pharmacopoeia, German Pharmacopoeia, Iranian Pharmacopoeia, and Indian Pharmacopoeia, if imported and domestically manufactured medicines' certificates of analysis adopt those specific pharmacopoeial standards. Food and Drug Quality Control Department has equipment that measures dissolution, disintegration, pH, and infrared and ultraviolet-visible spectra.

The Afghanistan National Standards Agency (ANSA) was established to set norms and standards for many products, including the safety and quality standards for foods. However, it has been determined that food safety and quality standards are outside ANSA's mandate and the responsibility belongs instead with the MoPH. Therefore, ANSA has transferred its analytical testing equipment to the Food and Drug Quality Control Department. ANSA had initiated work with various ministries and agencies to study and adapt *Codex Alimentarius*⁶ standards for edible oils and wheat, but those efforts have now been assigned to other agencies.

Gaps Identified

For medicines, although the country adopted internationally recognized pharmacopoeial standards, Food and Drug Quality Control Department's equipment and resources are inadequate to carry out full pharmacopoeial testing. Consequently, it is a significant gap that the regulatory standard cannot be confirmed or measured by the existing equipment.

For processed and retail food products, although the Food and Drug Quality Control Department uses the *Codex Alimentarius* as a basis for testing, the laboratory does not possess adequate apparatus and instrumentation to perform the full array of those tests. MAIL performs most of the microbiological testing on products of animal origin, although MAIL lacks sufficient staff to do all the required testing. Fruits and vegetables receive no safety tests for pesticide residue or heavy metals, and, in general, no safety monitoring is in place for fresh fruits and vegetables. Dried fruits and nuts are also not screened for mycotoxins or pesticide residues.

⁵ HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

⁶ The Codex Alimentarius Commission was established by the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) to protect the health of consumers and ensure fair practices in food trade. Codex is funded by FAO and the WHO and has 180 member governments, including the European Community as a member organization. Codex standards are adopted in most cases by consensus and are based on the best scientific and technical knowledge.

Level of Regulation

The MoPH has three branches, Technical Affairs, Administrative Affairs, and Health Services Provision. Various departments within the MoPH handle the following regulatory functions for both medicines and food products: policy formulation, regulation, inspection, quality control, surveillance, and enforcement (see Table 1). The organizational structure for regulating both processed food and medicinal products appears to be vertical and the chain of command is well defined.

Table 1. Regulatory Functions for Medicines and Food Products within the MoPH

Function	Medicines	Processed and Retail Food Products
Policy Formulation	Technical Affairs <ul style="list-style-type: none"> • GDPA General Director for Policy and Planning 	No formal mechanism
Regulation,	Technical Affairs <ul style="list-style-type: none"> ➤ GDPA 	Health Services Provision <ul style="list-style-type: none"> • Preventive Care & Primary Health Care (PHC) Department <ul style="list-style-type: none"> ○ Environmental Health Department
Inspection	Technical Affairs <ul style="list-style-type: none"> ➤ GDPA <ul style="list-style-type: none"> ○ Legislation Implementation Ensuring Department. 	Health Services Provision <ul style="list-style-type: none"> • Preventive Care & PHC Department <ul style="list-style-type: none"> ○ Environmental Health Department
QC	Technical Affairs <ul style="list-style-type: none"> ➤ Food & Drug Quality Control Authority 	Technical Affairs <ul style="list-style-type: none"> ➤ Food & Drug Quality Control Authority
Surveillance	Technical Affairs <ul style="list-style-type: none"> ➤ GDPA <ul style="list-style-type: none"> ○ Legislation Implementation Ensuring Department 	Technical Affairs <ul style="list-style-type: none"> ➤ GDPA <ul style="list-style-type: none"> ○ Legislation Implementation Ensuring Department Health Services Provision <ul style="list-style-type: none"> • Preventive Care & PHC Department <ul style="list-style-type: none"> ○ Environmental Health Department
Enforcement	Technical Affairs <ul style="list-style-type: none"> ➤ GDPA <ul style="list-style-type: none"> ○ Legislation Implementation Ensuring Department 	Technical Affairs <ul style="list-style-type: none"> ➤ GDPA <ul style="list-style-type: none"> ○ Legislation Implementation Ensuring Department Health Services Provision <ul style="list-style-type: none"> • Preventive Care & PHC Department <ul style="list-style-type: none"> ○ Environmental Health Department

All six regulatory functions for **medicinal products** are performed under the Deputy Minister for Technical Affairs. For day-to-day operational issues pertaining to pharmaceuticals, such as drug importation, registration, and procurement, the GDPA under the Technical Affairs Branch, has ongoing interactions with the Customs Office of the MoF, the Food and Drug Quality Control Department and the Legislation Implementation Ensuring Department within the same directorate.

In the pharmaceutical sector, the MoCI, the MoF (except for the Customs Department activities), and the Government Treasury are limited to collecting fees for drug sampling and issuing retail pharmacy licenses.

Although there is a mechanism in place for development, there are no formal policies or legislation related to **processed and retail food products**. However, the other regulatory functions are covered adequately, if not efficiently; for example, the Deputy Minister for Health Services Provision is responsible for regulation, sampling, and inspection of processed and retail food products, but shares the surveillance and enforcement functions with the

Deputy Minister of Technical Affairs. Because the branches report to different deputies, the transparency and effectiveness of communication between the two can be challenging without interagency agreements that better define roles and responsibilities. Quality control for processed and retail food products is handled by the Food and Drug Quality Control Department, which reports directly to the Deputy Minister for Technical Affairs of the MoPH and not to the Afghanistan Public Health Institute or to the Health Services Provision Branch, which is responsible for inspections and sampling.

In addition to the various departments within ministries that cover the regulatory functions, the NFMB, first established in 2001 as the National Medicine Board, then expanded to include food in October 2009, was created to be a more efficient entity to address and implement the rules and regulations pertaining to medicines and processed and retail food products.

Currently, the NFMB¹ is responsible for—

- Coordinating activities related to pharmaceuticals, testing equipment, processed and retail food products, cosmetics, sanitation equipment, traditional medicines, and preventing the production and importation of unsafe medicinal or food products. The NFMB may also make regulatory activity decisions, perform technical research, make technical recommendations, and suggest regulations to the MoPH.
- Acting as the highest body to deliberate and make recommendations on issues related to pharmaceuticals, testing equipment, processed and retail food products, cosmetics, sanitation equipment, and traditional medicines.
- Technically strengthening MoPH research activities related to medicine, food, cosmetics, sanitation equipment, and traditional medicines; developing and suggesting regulatory revisions to the Minister of Public Health on medicines, food, cosmetics, and sanitation equipment.

However, the NFMB lacks sufficient communication and coordination to effectively regulate food and drugs. Scheduling and security challenges in the country result in insufficient attendance to reach a quorum at meetings and a lack of access to technical experts prevents the board from making sound decisions on technical issues. In the absence of a mandate and authority, NFMB decisions might not be executed, which is exacerbated by lack of feedback on decisions or follow-up to assure implementation.

⁷ Islamic Republic of Afghanistan, Ministry of Public Health, General Directorate of Pharmaceutical Affairs, National Board of Food and Drug, Aqrab, 1388

RECOMMENDED INTERVENTIONS BASED ON THE ASSESSMENT FINDINGS

Based on the results of the regulatory assessment and identified gaps, SPS developed the following interventions to strengthen the regulation and control of food and medicinal products. In the following section, SPS presents a series of options for the MoPH to consider to strengthen the regulatory system for medicines and food products; however, SPS recommends that the following overarching interventions be implemented regardless of the options chosen because they are needed to form the foundation of a functioning regulatory agency.

Update Legislation

A review of the existing laws and regulations for drugs is needed to more clearly define roles, responsibilities, communications, and coordination. A functioning system is needed to develop legislation and regulation for processed and retail foods.

In Afghanistan, the Minister's office (Public Health, Justice, etc.) makes all regulations and legislation related to its responsibilities and activities. To expedite the development and eventual adoption of appropriate legislation, SPS proposes establishing a legislative assistant in the Office of the Minister of Public Health. The legislative assistant would collaborate with the NFMB to develop and facilitate the passage of appropriate processed food legislation and review existing drug laws and regulations to bring them up to current standards if needed.

Strengthen Quality Assurance Systems

A comprehensive strengthening of the quality assurance (QA) system is needed to improve the standards for all medicinal and food products. All stakeholders should be included in this process—faculties of pharmacy and agriculture, regulatory authorities, the domestic pharmaceutical industry, and food production plants. In addition, all stakeholders need to be educated and sensitized to the need for QA systems to protect the public from health hazards. Practices to consider incorporating into the QA system include Good Distribution Practices, Good Storage Practices, Good Laboratory Practices, Good Procurement Practices, and Good Manufacturing Practices.

GMP is the focus of discussion here because it falls within the realm of a drug regulatory authority. However, this does not imply that the other aspects of the good practices should be overlooked. In particular, Afghanistan is relying extensively on importing goods because its manufacturing capacity is less developed. Consequently, a well-functioning procurement program, a strong and robust distribution system, and adequate storage infrastructure to preserve the integrity of goods are required. These various components need to be examined and addressed.

Quality Control—GMP and HACCP

Regulatory inspection staff and manufacturers need to be oriented, and training materials and SOPs developed for implementation and enforcement. The faculties of agriculture at various campuses under contract with FAO, MoPH, and the MAIL have developed an extension program to train community workers and local communities on safe food processing (i.e.,

HACCP for the lay person). The pharmacy faculty can provide ongoing training in GMP for industry and the medicine regulatory unit(s). WHO could be a potential external training source in collaboration with the university and MoPH. The individuals hired to help strengthen quality control must be competent either in GMP for pharmaceuticals or in HACCP for foods. Fluency in Dari and possibly Pashto is also desired.

Laboratory Capacity and Infrastructure

The infrastructure at Food and Drug Quality Control Department is less than adequate to even minimally address the quality control testing needs for food products, medicines, and water. ANSA has transferred their food testing equipment to the Food and Drug Quality Control Department, but there is not enough space to install it. In addition, there is insufficient trained staff to implement the programs.

The current location of the Food and Drug Quality Control Department within the MoPH complex is meant to be temporary (the original laboratory was destroyed during the war in 2001). There are two recommended options for relocating the Food and Drug Quality Control Department. When the U.S. Embassy expands and takes over the MoPH complex, Food and Drug Quality Control Department could move to a renovated space at Avicena Pharmaceutical Institute, where the lab was formerly located. The Avicena Pharmaceutical Institute building can adequately house the testing facilities with renovation (see Annex 2 for photographs of Avicena Pharmaceutical Institute).

An alternate option is to move the laboratory to temporary quarters before settling into a permanent facility; this option would require a significant amount of time and resources to perform the required Installation Qualification¹ and Performance Qualification¹. Both qualification activities could take six months or longer and should be performed with every significant move to new facilities. This scenario essentially increases the effort and time two-fold because the laboratory needs to be moved twice; therefore, it is less desirable given the limited resources.

Regardless of the venue chosen for the relocation, extra space will allow for additional testing equipment and staffing and will subsequently improve efficiency and testing capacity. Given that the legal standards for medicines require complex and expensive equipment for analysis, that medicines are less perishable than foods, and that medicines are relatively easy to transport, it is feasible to send all medicinal products to the central laboratory in Kabul for testing. This will also build the capacity of the central laboratories for testing medicines. As the central laboratory builds capacity, it can then provide support to the regional laboratories and decentralize the workload as needed. Eventually, the central laboratory can function as a referral hub and a “steward” for standard setting and technical guidance. Although this intervention may require an extensive commitment of time and efforts, an intermediary intervention can bridge the gap: inexpensive and robust Minilabs[®], which can test over 40

⁸ Installation Qualification – It is performed to ensure all the needed resources and space available for the proper operation and maintenance are present—power, water, air handling, cooling, disposal, data systems, storage (gas, inflammable solvents, hazardous substances, controlled substances) etc.

⁹ Performance Qualification – It is performed to ensure the systems meet their required specifications after the installation, such as—all calibrations have been done, control systems in place and operational, sample handling systems are in place, etc.

active pharmaceutical ingredients, could be used at ports of entry to detect substandard or counterfeit medicinal products.

Because processed and retail food products are perishable and can be bulky to transport, establishing decentralized food testing resources at faculty of agriculture laboratories near ports of entry would be feasible. The MoPH could contract with the universities' faculties of agriculture. In exchange, some of these facilities might be upgraded to also support the analyses of imported and locally manufactured food products. The potential benefit is two-fold—teaching capacity can be enhanced by providing the laboratory support, and additional revenue can be generated by charging the MoPH for the analytical services provided. The decentralized testing programs would be extensions of the Food and Drug Quality Control Department, which would establish the quality system requirements for these programs, direct the surveys, set guidance on standards, and collect data for analysis and action by the national authorities.

Strengthen the Capacity of NFMB

The NFMB is not situated within the MoPH or GDPA organizational structure; it is a stand-alone, independent board that reports directly to the Office of the Minister of Public Health. By creating a position of secretariat within NFMB, it can better coordinate and triage activities in concert with the minister and various departments within the ministry, thereby improving the efficiency and productivity of the existing system. By revising the NFMB's mandates and terms of reference and allowing the secretariat to have the voice and authority of the minister, the board could be given decision-making authority. Establishing technical subcommittees and integrating already-existing committees to the NFMB structure would strengthen the board's capacity to make sound decisions with the backing of technical expertise.

Build Human Resource Capacity

Human resources are an essential factor that cuts across all departments with regulatory authority. Although this assessment did not evaluate human resource competency, it should not be overlooked. An evaluation on the human resource capacity should be conducted and the results shared with relevant stakeholders. Through various mechanisms, such as roundtable forums, consultancies, or consensus workshops, stakeholders should draft strategies for human resources planning, establish required skill sets, identify competency gaps and determine training needs.

Conduct a Total Diet Survey

Because dietary intakes vary across the regions of the country, dietary exposures to naturally occurring and/or synthetic toxic substances also vary. These exposures are determined through total diet surveys¹⁰, where the dietary intake of a population is submitted for analysis to determine its consumption and used to implement mitigation strategies to reduce undesirable exposures. The five main groups of food contaminants that total diet surveys

¹⁰ The total diet survey determines levels of contaminants and nutrients in foods. From this information, dietary intakes of those analytes by a population can be estimated. It can be used to monitor for radioactive contamination, pesticide residues, industrial chemicals, and toxic and nutrient elements. A unique aspect of the surveys is that foods are prepared as they would be consumed (table-ready) prior to analysis, so the analytical results provide the basis for realistic estimates of the dietary intake of these analytes.

evaluate are heavy metals, such as lead, pesticides, microbes, such as *Escherichia coli*, mycotoxins, such as aflatoxin, and chlorinated hydrocarbons, such as dioxins.

Such a survey requires significant resources including advanced analytical instruments, comprehensive sampling methodology to ensure that the population is sufficiently sampled and well represented, proper sampling preparation and chain of custody to preserve the integrity of the samples, and a functioning surveillance system to track the origin of contaminants. Therefore, in the absence such resources, SPS recommends postponing this intervention until the country has an adequate and functioning QA scheme, surveillance system, and regulatory body in place.

However, if external funding and technical support is available, this intervention could be initiated now. As a first step, a baseline estimate of the level of contamination in the Afghan diet needs to be established. This can be accomplished by contracting with regional laboratories, or selected laboratories at faculties of agriculture, to collect and prepare samples. For tests requiring sophisticated resources beyond what is available in-country, a competent external laboratory can analyze the samples. There are potential foreign resources that may be willing to assist, such as U.S. Food and Drug Administration, which has established extensive programs to support total diet survey activities.

The baseline assessment would help provide an idea of which toxic substances are a problem. Once the at-risk food products can be identified, the monitoring and regulatory focus can target those food groups. After the initial phase of prioritizing and improving the safety profile of the at-risk food products, the regulation and monitoring of the remaining groups of contaminants can be phased in.

Conducting total diet surveys on a regular basis provides information on the extent of contaminants exposure among the general public and allows the formulation of recommendations or interventions on diet change, handling, or processing changes in agricultural procedures. Based on the results, the total diet survey also functions as a cross-check mechanism to monitor the food supply chain and to ensure that the quality assurance systems for imported food products and locally manufactured / processed and retail food products are functioning.

While it is ideal to survey the general public, given the country's limited resources, a more practical and feasible monitoring target includes those food groups that are primarily consumed by infants, children, and women of child-bearing age.

RECOMMENDED OPTIONS TO STRENGTHEN REGULATORY CAPACITY

In addition to the proposed overarching interventions described above, the SPS Program proposes the following options to strengthen the regulatory capacity for food and medicines.

Option 1: Provide support to strengthen the NFMB's capacity

Option 2: Provide support to establish two separate regulatory entities with one enforcement agency

Option 3: Provide support to establish an independent AffFDA

As defined in WHO's *Effective Drug Regulation—A Multicountry Study*,¹¹ the options analysis took into consideration the following factors to develop an organizational structure and authority—

- **A government-run entity**—To maintain a neutral position by minimizing influences from private sectors, making unbiased decisions, and avoiding potential conflict of interests from individuals, groups, and the public.
- **A specialized entity**—An Agency exclusively deals with medicines and processed and retail food products; functions range from setting standards to enforcing them.
- **A centralized entity**—An agency/authority with vertical organization, which allows for efficient utilization of resources because the functions/activities performed for both medicines and food products are similar; centralized decision-making enhances the overall effectiveness of management and regulation.
- **An entity employs advisory boards/committees to provide technical support**—Actively involve academia, research institutes, and expert panels for technical advice and expertise for up-to-date information; improve standards and practices to benefit the health and well-being of the general public.

In identifying options to strengthen the regulatory capacity for food and medicines, the SPS consultants were guided by SPS's operational principles. The proposed options must—

- Be consistent with the national health strategy
- Build on existing structures and resources
- Build local capacity
- Complement, not duplicate, ongoing initiatives
- Leverage existing and potential resources

¹¹ WHO. 2002. *Effective drug regulation A multicountry study*. Geneva:WHO.

Option 1. Provide support to strengthen the NFMB's capacity

Overall Objective

Strengthen the capacity of the current board and enable the board with decision-making authority. Keep the existing regulatory infrastructure and functions intact; add additional resources to the current structures to enhance the activities that NFMB needs to perform as a functioning regulatory body.

Objective 1

Revise mandate and terms of reference for the NFMB.

The intervention strategy to achieve Objective 1 is to—

- Revisit the NFMB's original objectives and responsibilities through consensus building with current members and other stakeholders to re-define the functions and responsibilities
- Identify gaps where responsibilities fall short and find sustainable and feasible solutions by conducting a consensus workshop on the current appropriateness of the responsibilities
- Add a legal advisory assistant to help establish the mandate, authority and status
- Establish subcommittees by integrating already established committees related to the N DTC, CPDS, and pharmaceutical quality assurance system to address specific technical issues

Objective 2

Add a secretariat to the NFMB to function as a coordinator.

The intervention strategy to achieve Objective 2 is to—

- Establish a secretariat position to coordinate and triage activities in concert with the Minister of Public Health and the various regulatory departments within the MoPH; to bring about the required focus among the line managers to get the existing systems better coordinated and gain productivity to better achieve the goals; and to liaise with the subcommittees to address specific technical issues pertaining to processed food and medicinal products
- Have the voice and authority of the Minister of Public Health; able to make decisions on her behalf

Objective 3

Assure the safety of processed and retail food products, as well as improve the quality of medicines and processed and retail food products.

The intervention strategy to achieve Objective 3 is to—

- Sensitize and educate key stakeholders on the need for a quality assurance system for medicines and foods to protect the public from health hazards
- Use the NFMB to coordinate and facilitate the establishment, implementation, and enforcement of a GMP quality assurance scheme for the domestic manufactured medicine and a HACCP management system and *Codex Alimentarius* for processed foods manufacturers
- Require the NFMB to liaise with government departments and ministries to improve the communications among players involved in the quality assurance system

Objective 4

Keep the current organizational structure for medicines and food products intact, but strengthen the GDPA that is responsible for pharmaceutical products, the Environmental Health Department that is responsible for processed and retail food products, and the Food and Drug Quality Control Department that is responsible for quality control of medicines and processed food.

The intervention strategy to achieve Objective 4 is to—

- Strengthen the role of GDPA in the area of policy formulation, regulation, inspection, surveillance, and enforcement
- Update the policy on formulation of medicines to reflect the current situation and establish a strategy to address future needs
- Draft a policy and legislation for processed and retail food products to enable the establishment of a regulatory framework
- Revise /update the regulatory standard on drugs and processed and retail food products to reflect the current tests that can be performed with the existing testing equipment and identify mechanisms to monitor products that cannot be measured by the existing equipment
- Standardize, strengthen, and improve the efficiency of the inspectorate services for medicines and processed and retail food products
- Establish a postmarketing surveillance mechanism for medicine quality, adverse drug reactions, and product recall
- Strengthen the coordination between surveillance and testing units to increase their timely response to issues that may arise.
- Standardize enforcement measures and clearly define the authorities and status of enforcement agencies

Expected Outcomes

- Minimum disruption of the current structure and organization, which keeps morale up
- The addition of resources, which enhances the departments' capacities to perform the activities required for a well-functioning regulatory system
- The creation of a secretariat position, which promotes better coordination and cooperation among agencies and ministries

Anticipated Barriers

This option requires a well coordinated effort related to the regulatory functions for medicines and food products, which has not occurred thus far. Because the GDPA currently has separate management structures to regulate processed and retail food products and medicines, keeping the structure intact would mean that the inspectors and testing functions would not be under one line of management, resulting in inefficiencies.

Option 2. Help strengthen infrastructure and capacity and help integrate resources that can be shared between entities that control medicines and food products

Overall Objective

Keep the current organizational structure for medicines and food products intact, but strengthen the GDPA that is responsible for pharmaceutical products, the Environmental Health Department that is responsible for processed and retail food products; enhance the efficiency of regulatory functions by consolidating resources that can be shared between entities that control medicines and food products.

Objective 1

Keep the current organizational structure for medicines and food products intact, but strengthen the GDPA that is responsible for pharmaceutical products, the Environmental Health Department that is responsible for processed and retail food products, and the Food and Drug Quality Control Department that is responsible for quality control of medicines and processed food.

The intervention strategy to achieve Objective 1 is to—

- Strengthen the role of GDPA in the area of policy formulation, regulation, inspection, surveillance, and enforcement
- Update the policy on formulation of medicines to reflect the current situation and establish a strategy to address future needs
- Draft a policy and legislation for processed and retail food products to enable the establishment of a regulatory framework
- Revise /update the regulatory standard on drugs and processed and retail food products to reflect the current tests that can be performed with the existing testing equipment and identify mechanisms to monitor products that cannot be measured by the existing equipment

Objective 2

To improve efficiency, integrate the regulatory activities and functions that are identical to medicines and processed and retail food products.

The intervention strategy to achieve Objective 2 is to—

- Consolidate resources, including staffing and equipment for inspectorate and surveillance activities in the field operation
- Standardize enforcement measures for medicines and food products and clearly define the authorities and status of enforcement agencies

- Conduct staff training, as necessary, to build competency and knowledge based on regulatory activities that are identical in both medicines and processed food products
- Share an inventory list of testing equipment for medicines and food products; consolidate as appropriate
- Strengthen the coordination between surveillance and testing units to increase their timely response to issues that may arise
- Coordinate the regulatory functions for medicines and food products by developing interagency SOPs, to clarify roles, responsibilities, communications, and coordination within the system. The SOPs should focus on quality, efficacy and safety, and not on the relative power or existing routines of the agencies involved.

A coordinating body, such as NMFB, would best oversee the coordination between the regulatory and enforcement functions. Such a body should ensure the harmonization and consistency between setting standards for regulation and measuring standards for compliance and enforcement.

Expected Outcomes

- Maximized efficiency of enforcement activities, resulting from sharing the same resources for processed and retail food products and medicines
- Maintenance of the regulatory and legislative functions for processed food and medicines under different jurisdictions, which minimizes potential conflict of interest among the enforcement and regulatory bodies

Even though strengthening the quality assurance systems is not a specific objective in this option, it is an overarching intervention and should not be ignored.

Anticipated Barriers

This option requires a political will, well-coordinated effort among the agencies involved with regulatory and enforcement activities. With the existing lack of coordination, achieving the tasks required under this option would be challenging, unless a coordinator agency could function as a facilitator to liaise and oversee the various activities.

Objective 3

Set up a food regulatory function and a drug regulatory function under one umbrella regulatory authority with a single enforcement agency.

The intervention strategy to achieve Objective 3 is to—

- Coordinate the regulatory function for medicines and food products by clarifying roles, responsibilities, communications and coordination within the regulatory structure.
- Develop interagency SOPs focused on quality, efficacy and safety, not the relative power or existing routines of the agencies involved
- Consolidate resources for enforcing regulations for medicines and food products in the field
- Standardize the enforcement measures

- Coordinate with the Ministry of Justice to establish clear definition of the authority and status of the enforcement agency

A coordinating body, such as NMFB, would best oversee the coordination between the regulatory and enforcement functions. Such a body should ensure the harmonization and consistency between setting standards for regulation and measuring standards for compliance and enforcement.

Expected Outcomes

- Maximized efficiency of enforcement activities, resulting from sharing the same resources for processed and retail food products and medicines
- Maintenance of the regulatory and legislative functions for processed food and medicines under different jurisdictions, which minimizes potential conflict of interest among the enforcement and regulatory bodies

Even though strengthening the quality assurance systems is not a specific objective in this option, it is an overarching intervention and should not be ignored.

Anticipated Barriers

This option would also require a well-coordinated effort among the agencies involved with regulatory and enforcement activities. With the existing lack of coordination, achieving the tasks required under this option would be challenging, unless a coordinator agency could function as a facilitator to liaise and oversee the various activities.

Option 3. Provide support to establish an independent AfFDA

Overall Objective

To establish a semi-autonomous agency with separate funding sources to consolidate food and medicines regulatory functions. Through functional transfers, consolidate all MoPH regulatory functions into AfFDA. Establish the AfFDA within the MoPH, and have the NFMB become an advisory body to the AfFDA.

Objective 1

Consolidate the various food and medicines functions into a single agency.

The intervention strategy to achieve Objective 1 is to—

- Conduct a series of consensus-building workshops to discuss the functional transfers
- Establish functional statements, terms of reference, operational SOPs, and a management structure for the AfFDA
- Conduct staff training to conform to the new management structure and requirements
- Develop an implementation scheme and timeline for implementation,
- Collaborate with the MoF and the MoPH to establish a budget authority and financial scheme for sustaining the agency

Objective 2

Improve the quality control and assurance system for both processed and retail food products and medicines by strengthening the existing regulatory mechanism.

The intervention strategy to achieve Objective 2 is to—

- Work with key stakeholders, in both the private and public sectors, on the QA areas that need to be strengthened, including establishing, implementing, and enforcing standards such as GMP for medicines and the HACCP management system and *Codex Alimentarius* for processed foods
- Introduce and implement the other good practices within the quality assurance scheme, as appropriate, such as good distribution practices, good storage practices, good laboratory practices, and good procurement practices
- Introduce post-graduate continuing education courses (on-the-job training) and incorporate QA training courses as part of pre-service academic course work
- Establish a well-functioning and coordinated system to link the components of the quality control and quality assurance systems of medicines and processed and retail food products
- Improve the capacity of Food and Drug Quality Control Department, including staff competency and infrastructure

Expected Outcomes

- Establishment of AfFDA as the entity fully responsible for policy formulation, authority for regulating, inspecting, quality control, surveillance and enforcement of all processed foods, medicines, medical devices (equipment and supplies), biologics, vaccines, blood products, etc..
- Efficient use of resources to control all regulated products, including laboratory, inspection, surveillance, and enforcement
- Shift of resources that adjusts for changing regulatory needs, especially human resources and testing equipment; for example, staff can be trained in one inspection area, then expand into other regulated areas

Anticipated Barriers

As this option involves a potential disruption of the current structure and a change in the allocation of resources and support, the option would require strong political will and firm commitment and financial investment to justify the need to establish an independent medicines and food products regulatory authority. Creating an independent agency would require additional financial resources in addition to an upfront costs related to establishing enabling legislation.

Leveraging Existing and Potential Resources for Options

A number of existing stakeholders are carrying out initiatives or have interests in strengthening the pharmaceutical and food supply regulatory system. Following are some examples of donors and initiatives that may present opportunities for leveraging existing resources or adding new ones.

In the pharmaceutical sectors, the ongoing collaboration with the NFMB and the GDPA allows the USAID-funded SPS Program to further support the facilitation and establishment of a functional regulatory body. In addition to the U.S. government funding, non-U.S. funding mechanisms, such as Health Partners International of Canada funded by the Canadian International Development Agency, has committed funding to the Afghanistan pharmaceutical market to improve the inventory management and accessibility of medicines. Both the European Union and the World Bank also have funding earmarked to support various activities in the pharmaceutical sectors, such as improving quality, accessibility, and availability of medicines.

In the food sectors, the USAID-funded Trade and Accession Facilitation for Afghanistan (TAFA) project provides support in both the agricultural and non-agricultural sectors to advance the quality and safety standards of exported products.¹² The U.S. Department of Defense might also be a potential source for providing technical assistance in setting up laboratories to improve the food supply for the Afghan military.

In terms of technical support, both FAO and WHO have various activities in the country related to food and health, working in close collaboration with governmental and non-governmental stakeholders to build capacity in the public and private sectors.

¹² <http://afghanistan.usaid.gov/en/Activity.160.aspx>

NEXT STEPS

Next steps include the following—

- Establish a larger stakeholder forum to discuss the proposed options and to allow stakeholders to discuss the feasibility and sustainability of the suggested interventions corresponding to each proposed option. Stakeholders could include MoPH departments, other government ministries, academia, donor agencies, and implementing organizations.
- Identify an option based on the consensus among stakeholders.
- For the specific interventions in the option chosen, develop an implementation strategy, budget the cost of implementation and level of effort required for staffing, and identify resources needed.
- After the implementation strategy is established, transfer each intervention to an operational plan with a timeline for each stage of implementation.
- Establish indicators for monitoring and evaluation to track progress of the implementation strategy.

ANNEX 1. LIST OF PERSONS MET

Afghanistan National Standards Authority (ANSA)

Dr. Mujburrahman Khateer Technical Deputy Director General

COMPRI-A

Dr. Abdul Waheed Adeeb Training manager
Dr. Ebrahim Heidar Director General
Mr. Shaun O'Neil Deputy Center Director, Health Services and Systems
Mr. Russ Fortier Chief of Party
Dr. Syed Homayon Managing Director, Khalid Irshad Pharm Ltd.

Expanded Programme on Immunization (EPI)

Mr. Gula Khan Ayoub Communication Officer
Mr. Gula Gut Dost National EPI Manager

Food and Agricultural Organization of the United Nations (FAO)

Mr. Mohammad Aqa Assistant Representative
Ms. Silvia Kaufmann Food security, nutrition and livelihoods advisor

Health Partners International Canada (HPIC)

Mr. Alim Atarud Project Director
Ms. Kendall Nicholason Senior Director

Ministry of Agriculture, Irrigation and Livestock (MAIL)

Quality Control Agricultural Products Department

Mr. Azizullah Aimaq Director

Veterinary Department

Mr. Mohammad Ibrahim Frotan Veterinary advisor

Ministry of Commerce and Industry (MoCI)

Economic Growth and Governance Initiative

Ms. Monique Courchesne Deloitte Consulting LLP Advisor
Mr. Shoukatullah Khurram Afghanistan Central Business Registry IT analyst
Qasem Todayee Afghanistan Central Business Registry Advisor

Ministry of Public Health (MoPH)

Dr. Nour Safi Pharmaceutical Advisor/GDPA MoPH Advisor

Afghan Public Health Institute (APHI)

Dr. Bashir Noormal Director General

Environmental Health Department

Dr. Amanullah Hussaini Director
Mr. Wahid Food safety inspector

Food and Drug Quality Control Department

Dr. Kamela Sultani Director
Dr. Kamila Dindar Manager food and water department
Dr. Amena Rustaqi Manager medicines department

General Directorate Pharmaceutical Affairs (GDPA)

Dr. Anwary	Director General, Pharmaceutical Enterprise department
Dr. Mirza Mohammed Ayuby	Deputy director, Procurement & Registration
Mr. Sabrulhaq S	Sampling manager
Mr. Hafize Quraishi	Sampling manager

Health Management Information System (HMIS)

Dr. Mohammed Ashraf	National Consultant
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Mashkooor

Health Promotion Department

Dr. Rasocal Mofleh	Director
Dr. S. Hemat	Advisor

International Relations Department

Dr. Habibullah Ahmadzai	Director
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Legislation Implementation Ensuring Department

Dr. Sayad Ebrahim Kamel	Director
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Monitoring and Evaluation Department

Dr. Ibne Amin	Acting Director
Dr Fazal Ahmad Rahimi	National monitoring check list manager

Public Nutrition Department

Dr. Zarmina Safi	Director
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Trade and Accession Facilitation for Afghanistan (TAFA) Project

Mr. Leonidas Bill Emerson	TAFA Advisor
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DAI Afghanistan Small and Medium Enterprise Development (ASMED) Project

Ms. Michelle Morgan	Chief of Party
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Kabul University Faculty of Agriculture

Prof. Mohammad Yasin Mohsini	Dean, Faculty of Agriculture
Prof. Samadi	Deputy Dean, Professor of horticulture
Prof. Najibullah Hassanzai	Deputy Dean, Faculty of Agriculture

Kabul University Faculty of Pharmacy

Dr. Pohanwal Mohammad	Dean, Professor of pharmacognosy
Nassim Sediqi	
Dr. Aqa Mohammad Jakfar	Associate Professor, Head of the Pharmaceutics department
Dr. Qamaruddin Saifi	Department of food analysis, nutrition and biochemistry

World Health Organization (WHO)

Dr. Ahmed Ashfaq	Medical officer, primary health care
Dr. Ahmad Shah Pardis	National officer, essential medicines

ANNEX 2. PHOTOGRAPHS OF AVECINA PHARMACEUTICAL INSTITUTE

API Front Entrance

Inside API, one floor section of the laboratory rooms, with exposed beams

Inside API, laboratory room, industrial grade structure with exposed pipeline

Inside API, laboratory room 1 – previously used for “cosmetics section”.

ANNEX 3. MEMBER LIST OF THE NATIONAL MEDICINE AND FOOD BOARD (NMFB)

Members

1. The Minister of Public Health, as head of the board
2. General Director of Pharmaceutical Affairs, as deputy head
3. Director of Avicenna Institute, as member
4. Two lecturers of Faculty of Pharmacy, as members
5. One member of Pharmacology Department of Kabul Medical University, as member
6. Procurement and Registration Department, as member
7. Head of Pharmacy Enterprises, as member
8. Head of Food and Drug Department, as member
9. One Internal Specialist from a hospital selected by the Minister of Public Health, as member
10. Head of Legislation implementation Ensuring Department, as member
11. One Surgical Specialist from a hospital selected by the Minister of Public Health, as member
12. Representative of the National Union of Drug Importers, as member
13. Representative of the National Union of Drug Producers, as member
14. Head of Monitoring and Evaluation Department, as member
15. Head of Environmental Health Department, as member
16. Head of Public Nutrition Department, as member

Observers

1. Focal Point for Food and Drug Section of National Office of Norms and Standards
2. Representatives of WFP, FAO, WHO and UNICEF
3. Focal Point for Food Control of the Ministry of Agriculture
4. Representative of the Ministry of Commerce
5. Representative of Chambers of Commerce
6. Representative of Traditional Treatment Union