



Islamic Republic of Afghanistan
Ministry of Public Health
National Medicines and Food Board

**Strategic Framework for the National
Medicines and Food Board (NMFB)**

2013 - 2016

May 2013

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Abbreviations

API	Avicenna Pharmacy Institute
EDL	Essential Drug List
FC	Food Committee
FDA	Food and Drug Administration
GDPA	General Directorate for Pharmaceutical Affairs
GMP	Good Manufacturing Practice
LDL	Licensed Drug List
MC	Medicines Committee
MoPH	Ministry of Public Health
NMB	National Medicine Board
NMFB	National Medicines and Food Board
NMP	National Medicine Policy
SOPs	Standard operating procedures
SPS	Strengthening Pharmaceutical System Project
SRA	Stringent regulatory (medicines) authorities
USAID	U.S. Agency for International Aid
WHO	World Health Organization

FOREWARD

I am pleased to present the first Strategic Framework of the National Medicine and Food Board (NMFB) of the Ministry of Public Health (MoPH) 2013-2016. The framework is the result of a collaborative effort among the NMFB members, the Food and Medicine committees of the NMFB and national and international partners including donors, NGOs and the public and private sectors since the establishment of the NMFB.

After the successful development of the NMFB Terms of References (ToR) in 2011, to operationalize the NMFB ToR, the Strategic Framework which is yet another landmark in the development and strengthening of the food and medicine regulatory systems, was developed.

The Strategic Framework 2013-2016 is developed to assure the safety, efficacy and quality of medicine and food, and sets the foundation for movement toward a transparent, responsible and equitable food and medicine regulatory systems. This framework identifies 4 strategic directions: (1) Appropriate operational framework for regulatory activities; (2) Financing & sustainability; (3) Capacity building strategies; (4) System performance;

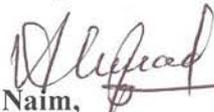
These strategic directions are the priorities that will guide the NMFB work over the next three years. This framework is supported by a Result Framework that will enable the NMFB to assess and report on the results of its activities within each Strategic Direction on a regular basis. The NMFB will develop new operational plans for attaining the strategic directions.

Successful implementation of this strategic framework will require the sustained involvement and inputs of many partners and stakeholders. Within the course of implementation of this strategic framework it will be acceptable to take note and allow essential adjustments to maximize outputs.

I would like to acknowledge the participation of all NMFB and its committee's members for their enthusiasm, commitment and collaboration. In addition, I would like to thank USAID and Strengthening Pharmaceutical Systems (SPS) project for technical facilitation and financial support.

Finally, it is my pleasure once again to call upon all stakeholders and our development partners in these vital sectors to join hands with government in an effort to successfully implement this three-year framework.

Sincerely,



Dr. Ahmad Jan Naim,
Deputy Minister for Technical Affairs
Ministry of Public Health

Executive Summary

Introduction

This document presents the National Medicines and Food Board (NMFB) strategic plan 2013 – 2016. The document seeks to provide a strategic framework for the achievement of the NMFB’s mandate, which is, to coordinate, advice and oversee the regulation of the pharmaceutical and food sector thus ensuring access to affordable, safe and effective quality assured medicines & related products, and food safety. The plan has been developed through consultations and involvement of the members of the NMFB Board and it’s two Committees and other stakeholders. The NMFB was established in 2009 and replaced the National Medicine Board (NMB), as its mandate was extended to include processed food products. According to the Medicine Law (2008), the Board is the highest decision making entity on issues related to pharmaceuticals.

Situational Analysis

The Ministry of Public Health is currently developing food laws and regulations for effective regulation and control of the sector ensuring food safety and quality of processed food on the market. The memorandum of understanding between the Ministry of Agriculture Irrigation and Livestock and the Ministry of Public Health and the introduction of the new food laws, is expected to clearly define the roles and responsibilities to improve food control and food safety. The current Medicine Law of 2008, which is the main legal instrument for the regulation of the pharmaceutical sector, is considered to be inadequate and is currently under review. Furthermore, the regulation of the pharmaceutical sector is considered to be weak based on international benchmarking. The system is characterised by fragmentation with different departments involved in different aspects of pharmaceutical regulation, lack of coordination among these departments, inadequate resources (human, financial & technical) for effective regulation, lack of appropriate technical standards e.g. guidelines and poor implementation of provisions of the current law., among other issues.

Vision, Goal, Values and Principles

<i>Vision</i>	Ensuring the safety, effectiveness and quality of medicines and food in Afghanistan
<i>Overall Goal</i>	To ensure the safety, quality, and effectiveness of pharmaceuticals, medical devices, cosmetics, sanitation equipment and traditional pharmaceuticals (medicines), as well as to ensure the safety and quality of food products and prevent their unnecessary and unsafe production, manufacture, importation, distribution, sale and use in Afghanistan
<i>Values & Principles</i>	Protect the public health Ensure safety, effectiveness and quality of imported and locally produced medicines Ensure the quality of imported and locally produced food and balanced diet Reducing the environmental risks Protect Human Dignity Equity in providing of health services Reducing health financial risks

Strategic Directions

S/No.	Objective	Key Strategies
1.	To ensure an appropriate operational framework for medicines & food by 2016	<ul style="list-style-type: none"> • To facilitate & coordinate the update or development of National Policies such as National Medicines Policy, Quality Assurance Policies both for food and medicine, National Food Policy and national food (safety) control strategy. • To facilitate & coordinate the development or update of the legal framework for medicines & food • To facilitate & coordinate information sharing among the regulator and implementers on pharmaceutical & food related issues • To develop minimum standards & requirements for the pharmaceutical & food sector and for the regulation of medicines & food
2.	To promote & facilitate capacity building for medicines & food regulatory systems	<ul style="list-style-type: none"> • Identification, creation and maintenance of a database of local experts in pharmaceutical & food regulatory sectors by 2016 • To facilitate & coordinate capacity building initiatives for the implementing institutions or departments, industry & NMFB & its Committees.
3.	To ensure 60 % of funding needs are met by 2016	<ul style="list-style-type: none"> • To facilitate or coordinate the development of strategic plans including budget for the implementing institutions or departments • To coordinate the support (technical, financial) for the regulation of medicines & food • Identification, creation & maintenance of database of support for medicines & food • To facilitate & coordinate the mobilising of resources for regulation of medicines & food
4.	To promote & facilitate system performance for medicines & food regulation	<ul style="list-style-type: none"> • To develop performance indicators for the regulatory systems for medicines & food • Identify constraints & challenges in pharmaceutical & food sector and address them • Recall and traceability system development

Implementation Framework

The plan will be implemented within the existing policy, regulatory, institutional, coordination, and monitoring and evaluation frameworks. Specific measures will be pursued, aimed at reviewing and strengthening all these frameworks, to ensure successful implementation of the plan. Implementation of the Strategy will follow the principles of results based management with a focus on achieving specific outputs and outcomes, timely and efficiently.

1. Introduction

The Ministry of Public Health (MoPH) is responsible for all public healthcare issues including ensuring that medicines distributed in the country are safe, effective and of good quality and ensuring food safety. There is both public and private sector involvement in provision of health care services. To this end the MOPH re-launched the National Medicines and Food Board (NMFB) to provide policy advice, coordinate and oversee the pharmaceutical and food sector. While it is recognized that the pharmaceutical and food regulation is generally weak, the MoPH has made some progress to strengthen the system including the ongoing development and /or revision of the legislation for both medicines and food and strengthening the NMFB.

This document presents the NMFB's strategic plan 2013 – 2016. The plan seeks to provide the strategic framework for effecting one of the aims of the MoPH, to achieve equitable, affordable, and sustainable quality support services, including those for pharmaceuticals.

The aim of this strategy is to facilitate an appropriate operational framework for medicine and food regulation, sustainable financing, capacity building initiatives and performance of the regulatory thus ensuring access to affordable, safe, effective and quality-assured pharmaceutical and food products.

2. Background

The pharmaceutical regulatory situation in Afghanistan is generally considered to be weak with most of the activities in the private sector and to a large extent in the public sector largely uncontrolled. With the very little local pharmaceutical production, most medicines used in the country are imported from neighbouring countries. The world pharmaceutical market has been changing radically. There has been a massive increase in low cost generic pharmaceutical manufacturing in Asia. In contrast to the 1990s, the origin of medicines in use in most developing countries today is now far more likely to be from the Asian region. For Afghanistan, medicines origins are notably China, India, Iran, and Pakistan; none of which countries are regarded as having stringent regulatory (medicines) authorities (SRAs).

The upshot of this situation is that it is now more difficult to control the quality of imported medicines, and greater regulatory oversight is necessary. Presently, regulatory functions are scattered in different departments or directorates with minimal or no coordination or communication among them. In the current world pharmaceutical situation there is clearly a need for a strengthened policy and regulatory environment to help to protect against counterfeit medicines. Currently, the total Afghanistan government and per capita expenditure for the pharmaceutical sector are not reliably known. The same is true for the total value of domestic pharmaceutical production and imports and exports of active pharmaceutical ingredients and finished pharmaceutical products. This is attributed to the lack of a database or credible source for collecting this information.

Regulation of the food sector and ensuring food safety has been adhoc in the absence of a legal framework. A draft food law is in the process of being finalised and will bring some clarity and empower the MoPH to effectively regulate food products to ensure food safety and quality.

2.1 Process

This plan has been developed by NMFB. The strategic planning process included the following main stages:

- Preparation of Draft NMFB Strategic Plan 2013 – 2016
- Review of the draft strategic Plan by the NMFB members
- Review & approval of the strategic plan by the NMFB
- Approval of the NMFB Strategic Framework 2013-2016 by HE Minister of Public Health.

2.2 Background to the establishment of the NMFB

The National Medicines & Food Board (NMFB) was established in 2009 and replaced the National Medicine Board (NMB), which was established in 2003. According to the Medicine Law (2008), the Board is the highest decision making entity on issues related to pharmaceuticals. Upon its expansion in 2009, the Board's mandate was extended to include foodstuff. According to the current Terms of Reference of the Board as approved by HE Suraya Dalil, Minister of Public Health in November 21, 2011, the Board's mandate is to advise, coordinate, oversee and accelerate medicines and food-related activities, and implement basic principles on the affairs related to the regulation of pharmaceuticals, medical devices, cosmetics, sanitation equipment and traditional pharmaceuticals (medicines) to ensure their safety, quality, efficacy and effectiveness, as well as to ensure the safety and quality of food products and prevent their unnecessary and unsafe manufacture, importation, distribution, sale and use.

2.3 Role and functions of the National Medicines & Food Board (NMFB)

To achieve the mandate of the NMFB, the Board shall:

1. Develop and review the bills and regulations / procedures related to pharmaceuticals, medical devices, food products and ingredients, cosmetics, sanitation equipment, traditional medicines, medical and food technology, chemicals (Reagents, precursors and reference standards).
2. Determine Committees for revision of Essential Drug List (EDL), Licensed Drug List (LDL) and Afghanistan National Formulary and other scientific and professional Committees related to pharmaceutical and food affairs.
3. Review the total Licensed Drug List
4. Regulate, monitor and coordinate all activities related to medicines and food
5. Establish and maintain effective recall systems for medicines and food.
6. Provide strategic direction for the regulation of medicine and food products
7. Embark on resource mobilization for regulatory activities for medicines and food products
8. Coordinate all relevant stakeholders/ authorities involved in medicines and food industry
9. Provide necessary support for establishing standard systems for medicines and food
10. Ensure the quality and necessary capacity for delivery of services related to medicines and food
11. Take a leading role in resolving medicines and food related problems
12. Develop the standard List of Food ingredients in accordance to Codex Alimentarius

13. Monitor the activities of Avicenna Pharmacy Institute (API) according to the relevant legislative document;
14. Review the Licensed Drug List (LDL) in accordance with the objective professional opinion of the relevant departments;
15. Review the licensed medicines list every three years using approved Committees of the Board;
16. Review and approve the Afghanistan National Formulary regularly
17. Approve scientific and research programs related to pharmaceutical products and food.
18. Approve regulations (Laiha) and operating procedures related to pharmaceutical and food affairs
19. Review and approve the country's annual need for medicines;.
20. Supervise all pharmaceutical and food services provision systems in the country;.
21. Approve bills to prevent the production and importation of unhealthy and unsafe food and beverages.

3. Rationale

The regulation of pharmaceuticals & food is fragmented with several implementing institutions or departments. The NMFB was established to provide coordination, oversight and advisory services in relation to the regulation of medicines and food products. The NMFB shall ensure that any food manufactured or imported is safe and healthy, and that medicines manufactured or imported is safe, efficacious, and of good quality. The NMFB will achieve this by working with existing implementing institutions or departments within the Ministry of Public Health & Ministry of Agriculture, Irrigation & Livestock among other government Ministries & departments.

4. Values and Principles

- a) Protect the public health
- b) Ensure safety, effectiveness and quality of imported and locally produced medicines
- c) Ensure the quality of imported and locally produced food and balanced diet
- d) Reducing the environmental risks
- e) Protect Human Dignity
- f) Equity in providing of health services
- g) Reducing health financial risks

5. Vision

Ensuring the safety, effectiveness and quality of medicines and food in Afghanistan

6. Purpose

The Purpose of the NMFB Strategy is to contribute to improved availability and access to affordable, quality, safe, & efficacious essential medicines and to ensure food safety in Afghanistan.

7. Strategic Objectives

The following strategic objectives shall allow NMFB to achieve the vision, purpose and expected results of this Strategic Framework:

1. To ensure an appropriate operational framework for medicines & food by 2016
2. To ensure 60 % of funding needs are met by 2016
3. To promote & facilitate capacity building for medicines & food regulatory systems
4. System performance

8. Strategic Direction

The strategic directions for this plan are guided by the existing key policy documents such as National Health Policy and Strategy, National Medicines Policy 2013 – 2018 and the Health and Nutritional Policy 2012-2020, which specifically mentions strengthening the capacity in regulating the pharmaceutical sector through different mechanisms of quality assurance. In this respect, the proposed objectives, outcomes, strategies, outputs and targets have been analysed in accordance with the following:

- Appropriate operational framework for regulatory activities;
- Financing & sustainability;
- Capacity building strategies;
- System performance;

This strategic plan takes note of the existing situation and trends, with respect to medicines & food regulatory activities, and seeks to propose objectives and strategies that would help address the existing weaknesses and threats, and ensure adequate strengthening of medicines & food regulatory systems in Afghanistan

8.1. Appropriate operational framework for regulatory activities

8.1.1. Overview

An appropriate operational framework is required for successful implementation of medicines & food regulation. This will include, policy and legal framework; organization of activities and implementing structures or institutions for regulatory activities, and appropriate standards such as scientific guidance, standards for processes & procedures and mechanisms for communication & accountability.

The main problems and gaps affecting the establishment of appropriate operational frameworks include:

- appropriate legal framework;
- fragmented & uncoordinated implementing structures
- financial resources

During the course of this plan, significant efforts will be directed at establishing and strengthening the operational framework, by utilising the existing structures & systems and

the opportunities present. In this respect, key national policies such as national medicines policy will be developed or updated, legal framework for both medicines & food (laws & regulations), and minimum standards for regulatory systems will be developed and support provided to implementing departments or institutions for implementation.

8.1.2. Objective

To ensure an appropriate operational framework for medicines & food by 2016

8.1.3 Outcomes, Key Strategies, Outputs, Indicators and Targets

S/No.	Outcomes	Key Strategies	Outputs	Indicators/Targets
1	Key national policies identified, developed & approved	1. Identify key national policies to be updated or developed	List of policies to be updated or developed	List of policies to be updated or developed including timelines by 2013
2	A legal framework for medicines & food developed and approved.	2. Finalise & approval of Food Law	Finalised Food Law	Food Law finalised & signed into Law by 2016
		3. Finalise the development & approval of Medicine Law	Finalised Medicine Law	Medicine Law finalised & signed into Law by 2016
		4. Identify & prioritise the food & medicine regulations to be developed to support the Food & Medicine Law	Priority List of Medicine & Food Regulations and Bills	A priority List of Medicines & Food Regulations & Bills by 2013
		5. Development & finalisation of food & medicine regulations	Finalised food & medicine regulations based on priority list	Medicine & Food regulations (based on priority list) approved by 2016
3	Minimum standards for medicine and regulatory activities developed & approved	6. Development & approval of technical guidelines, procedures and SOPs for medicines & food	Technical guidelines for medicines & food developed (registration, GMP, food safety)	Key guidelines for medicines & food developed & approved by 2016
		7. Procedure for licensing of food establishments and	Procedure for licencing developed and publicly	Procedures for licensing developed and publicly

S/No.	Outcomes	Key Strategies	Outputs	Indicators/Targets
		issuing health certificates	available	available by 2014
4	Coordinated system for pharmaceuticals & food sector	8. Develop mechanism for regular information sharing among implementers & stakeholders in the food and pharmaceutical sector	Established of coordination working groups that meet on regular basis for information sharing & coordination	# of monthly/quarterly meetings of working groups # of monthly/quarterly reports submitted to NMFB from the coordination working groups
		9. Identify constraints for information sharing and address them	Constraints identified and addressed	On-going constraints identified and addressed

8.2. Capacity Building

8.2.1. Overview

Current challenges of human resources have a considerable negative impact on the efficiency and effectiveness of medicines & food regulatory work. These capacity constraints relate to adequate number of professional staff, technical knowledge and expertise. During the course of this plan, significant efforts will be directed towards coordinated capacity building strategies taking into account the existing situations and intended strategic directions in strengthening the system.

8.2.2. Objective

To promote & facilitate capacity building for medicines & food regulatory systems

8.2.3. Outcomes, Key Strategies, Outputs, Indicators and Targets

S/No.	Outcomes	Key strategies	Outputs	Indicators/Targets
1	Establishment of a database of experts in different areas in pharmaceutical & food regulation	1. Creation & maintenance of a database of experts	A mapping of local expertise conducted	Database of individual experts by 2016
2	To facilitate & coordinate capacity building initiatives for	2. In country capacity building or	# of capacity building/trainings	At least three capacity building sessions in

S/No.	Outcomes	Key strategies	Outputs	Indicators/Targets
	the implementing institutions or departments, industry & NMFB & its Committees.	training activities conducted	conducted	medicine sector conducted annually At least three capacity building sessions in food sector conducted annually
		3. Facilitate training attachment of staff	Training conducted	At least 80% of planned trainings conducted

8.3. Financing & Sustainability

8.3.1. Overview

In order to better regulate the pharmaceutical & food sector, there is need for developing adequate funding mechanisms that are sustainable in the long term. Currently, the pharmaceutical sector and the country at large are largely dependent on donor or external financial support. In the short to medium term, the pharmaceutical and food sector will continue to depend largely on donor or external support while developing long term sustainable funding mechanisms.

8.3.2. Objective

To ensure 60 % of funding needs are meet by 2016 by mobilising resources from donor/partners and the government.

8.3.3. Outcomes, Key Strategies, Outputs, Indicators and Targets

S/No.	Outcomes	Key Strategies	Outputs	Indicators/Targets
1	To facilitate or coordinate the development of strategic frameworks including budget for the implementing institutions or departments	1. To facilitate and coordinate the development of strategic frameworks including budgeting for the implementing institutions or departments	Strategic frameworks developed	80% of the institutions or departments with approved strategic frameworks by 2016
	To coordinate the	2. Establish periodic	Quarterly/annual	80% reporting by

S/No.	Outcomes	Key Strategies	Outputs	Indicators/Targets
2	support (technical, financial) for the regulation of medicines & food	updates and receive reports from partners on areas supported quarterly/ annually	reports on support available and received	partners by 2016
3	Identification, creation & maintenance of database of support for medicines & food	3. Develop a list of partners, areas supported and amount	List of partners/donors & areas supported	A updated list of partners/donors developed by 2016
		4. Identify potential partners & areas for support	# of new partners identified and engaged	% of supporting coming from new partners by 2016
4	To facilitate & coordinate the mobilising of resources for regulation of medicines & food	5. Mobilise resources from the government (advocacy) for budgetary support	50% funding received from government	50% funding from government budget by 2016
		6. Mobilise resources from partners (existing & potential) for funding identified priority areas	25 % funding received from donors/partners	25% funding from partners/donors by 2016

8.4. System performance

8.4.1. Overview

According to the current ToR of NMFB, the NMFB is the advisory, oversight and coordination body for medicine and food regulatory sectors. In order to achieve the objectives of good quality, safe and effective medicines and food safety, there is need for performance monitoring of the regulatory system. This can be achieved through use of key performance indicators, identify and address constraints and to by ensuring transparency and accountability in the system.

8.4.2. Objective

To promote and facilitate medicine and food regulatory system performances

8.4.3. Outcomes, Key Strategies, Outputs, Indicators and Targets

S/No.	Outcomes	Key Strategies	Outputs	Indicators/Targets
1	To develop performance indicators for the regulatory systems for medicines & food	1. Develop performance indicators for medicines regulation	Performance indicators developed	Performance indicators developed & used by 2016
		2. Develop performance indicators for food regulation		Performance indicators developed by 2016
2	Identify constraints & challenges in pharmaceutical & food sector and address them	3. Identify constraints and address them	Constraints identified and addressed	On-going constraints identified and addressed
3	Transparent and accountable system for medicines and food regulation	4. To facilitate and promote accountability and transparency	To publish and make public available its semi-annual or annual reports	Semi-annual or annual reports public available by 2013

9. Results Framework

Strategic Objective 1: To ensure an appropriate operational framework for medicines and food by 2016							
Outcomes	Key strategies	Outputs	Indicators/Targets	Means of verification	Responsible	Estimated Budget (US\$)	Risks/ Assumptions
Key national policies for food and medicine identified, developed and approved	1. Identify key national policies to be updated or developed	List of policies to be updated or developed	List of policies to be updated or developed including timelines by 2014	Quarterly/Annual/Progress reports	NMFB Secretariat	140000	Information is readily available
A legal framework for medicines and food developed and /or updated	2. Finalise & approval of the Food Law	Finalised Food Law	Food Law finalised and signed into Law by 2014	Quarterly/Annual/Progress reports	FC, Board	7000	Political commitment, availability of technical & financial resources
	3. Finalise the development & approval of the Medicine Law	Finalised Medicine Law	Medicine Law finalised & signed into Law by 2016	Quarterly/Annual/Progress reports	MC, Board	39000	Political commitment, availability of technical & financial resources
	4. Identify & prioritise the food and medicine regulations and bills to be developed to support the Food & Medicine Law	Priority List of Medicine & Food Regulations and Bills	A priority list of medicines & food regulations and bills by 2013	Quarterly/Annual/Progress reports	NMFB Secretariat, Board	2000	Consensus on priority areas for regulations & bills
	5. Development & finalisation of food	Finalised food and medicine regulations	Medicine and food regulations and bills	Quarterly/Annual/Progress	MC, FC & Board	60000	Political commitment,

	and medicine regulations and bills	and bills based on priority list	approved by 2016	reports			availability of technical & financial resources
Minimum standards for medicine and regulatory activities developed and approved	6. Develop and approval of technical documents including guidelines and procedures	Technical guidelines for medicines & food developed (registration, GMP, food safety)	Key guidelines for medicines & food developed and approved by 2016	Quarterly/Annual/Progress reports	MC, FC, Board	30000	Availability of technical expertise, financial resources
	7. Procedure for licensing of food establishments and issuing health certificates	Procedure for licensing developed and publicly available	Procedures for licensing developed and publicly available by 2014	Quarterly/Annual/Progress reports	FC, Board	12000	
Coordinated system for pharmaceuticals and food sector	8. Develop mechanisms for regular information sharing among implementers and stakeholders in food and pharmaceutical sector	Establishment of coordination working groups that meet on regular basis for information sharing and coordination	# of monthly/quarterly meetings of working groups # of monthly/quarterly reports submitted to the NMFB from the coordination working groups	Quarterly/Annual/Progress reports	MC, FC, Board	60000	Key implementers, partners & stakeholders, interested & participate
	9. Identify constraints for information sharing and address them	Constraints identified and addressed	On-going constraints identified and addressed	Quarterly/Annual/Progress reports	MC, FC, Board	-	Technical expertise to identify & develop practical solutions, commitment

Strategic Objective 2: To promote and facilitate capacity building for medicines and food regulatory systems							
Outcomes	Key Activities	Outputs	Indicators/Targets	Means of verification	Responsible	Estimated Budget (US\$)	Risks/Assumptions
Establishment of a database of experts in different areas in pharmaceutical and food regulation	1. Creation and maintenance of a database of experts	A mapping of local expertise conducted	Database of individual experts by 2016	Functional database	NMFB Secretariat	15000	Availability of local expertise in regulation of food & pharmaceuticals
To facilitate and coordinate capacity building initiatives for the implementing institutions or departments, industry and NMFB	2. In country capacity building or training activities conducted	# of capacity building / trainings conducted	- at least 3 capacity building sessions (total target 100 people) in pharmaceutical sector conducted annually - at least 3 capacity building sessions in food sector conducted annually	Quarterly/Annual/Progress reports	FC, MC, Board	90000	Availability of trainees & trainers, financial resources
	3. Facilitate training attachment of staff	Training conducted	At least 80% of planned trainings conducted	Quarterly/Annual/Progress reports	FC, MC, Board	60000	Availability of financial resources

Strategic Objective 3: To ensure 60% of funding needs are met by 2016 by mobilising resources from donor/ partners and the government							
Outcomes	Key Activities	Outputs	Indicators/Targets	Means of verification	Responsible	Estimated Budget (US\$)	Risks/ Assumptions
To facilitate or coordinate the development of strategic plans including budget for the implementing institutions or departments	1. To facilitate and coordinate the development of strategic plans including budgeting for the implementing institutions or departments	Strategic plans developed	80% of the institutions or departments with approved strategic plans by 2016	Quarterly/Annual/Progress reports	FC, MC, Board	50000	Implementing departments interest, political commitment
To coordinate the support (technical, financial) for the regulation of medicines and food	2. Establish periodic updates and receive reports from partners on areas supported quarterly / annually	Quarterly / annual reports on support available and received	80% reporting by partners by 2016	Quarterly/Annual/Progress reports	NMFB Secretariat	7000	Partners or donors interested & participation, knowledge of all partners involved
Identification, creation and maintenance of database of support for medicines and food	3. Develop a list of partners, areas supported and amount	List of partners/donors and areas supported	Update list of partners/donors developed by 2016	Quarterly/Annual/Progress reports	NMFB Secretariat	5000	Knowledge of all partners involved
To facilitate and coordinate mobilising of	4. Mobilise resources (advocacy) for budgetary support to	% increase in funding received from government	50 % increase in funding from government budget	Quarterly/Annual/Progress reports	Board	-	Political commitment

resources for regulations medicine and food	MOPH		by 2016				
	5. Identify potential partners and areas for support	# of new partners identified and engaged	25 % of support coming from new partners by 2016	Quarterly/Annual/Progress reports	FC, MC & Board	-	Knowledge of potential partners and areas of support

Strategic Objective 4: To promote and facilitate system performance for medicines and food regulation							
Outcomes	Key Activities	Outputs	Indicators/Targets	Means of verification	Responsible	Estimated Budget (US\$)	Risks/Assumptions
To develop performance indicators for the regulator systems for medicines and food	1. Develop performance indicators for medicines regulation	Performance indicators developed	Performance indicators developed and used by 2016	Quarterly/Annual/Progress reports	MC, Board	15000	
	2. Develop performance indicators for food regulation	Performance indicators developed	Performance indicators developed by 2016	Quarterly/Annual/Progress reports	FC, Board	15000	
Identify constraints and challenges in pharmaceutical and food sector and address them	3. Identify constraints and address them	Constraints identified and addressed	On-going constraints identified and addressed	Quarterly/Annual/Progress reports	FC, MC, Board	-	Availability of knowledge and expertise
Transparent and accountable system for medicines and food regulation	4. To facilitate and promote accountability and transparency	To publish and make publicly available semi-annual and annual reports	Semi-annual or annual reports publicly available by 2013	Semi-annual and annual reports	Board	10000	Political support

10. Coordination and Implementation of the Strategy

10.2. Institutional Arrangements

Policy oversight will be provided by the Minister of Public Health and Government. The Minister of Public Health will approve major policy and budgetary issues in relation to operationalizing the Strategy. The Strategy reflects issues that go beyond the mandate of just the NMFB as an advisory, coordinating & oversight Board. Implementation will therefore be in collaboration between multiple departments and institutions such as Quality Control Laboratory, General Directorate of Pharmaceutical Affairs, Directorate of Environment Health, Public Nutrition Department and other stakeholders. The Board of the NMFB & the Minister of Public Health will approve the Strategy as well as facilitate implementation at the national level.

Under the leadership of the NMFB Chairperson, the Secretariat will coordinate activities related to the implementation, monitoring and evaluation of the Strategy. This will be done with financial and technical assistance provided by partners.

The NMFB Board will oversee the implementation of the Strategy.

10.3. Operational Arrangements

The NMFB Secretariat will coordinate the activities outlined in this Strategic Framework.

11. Monitoring and Evaluation

The Results Framework of the Strategy will form the main M&E tool, which is guided by the principles of Results-Based Management (RBM) and by the MOPH or Government of Afghanistan Policy on M & E. The objectives of the monitoring and evaluation mechanism of the Strategy are to:

- Ensure that the outputs and outcomes are being achieved as planned.
- Provide regular information to all stakeholders on progress that would, among others, inform the basis for any reviews.

12.1 Output monitoring

In line with the Results Framework of the Strategy, the NMFB , with support from technical partners will put in place the following measures to ensure implementation of planned activities and delivery of outputs:

1. Develop relevant M&E tools and templates that will guide the collection, analysis, dissemination and utilization of data on key indicators and targets;
2. Conduct periodic review meetings of relevant stakeholders to assess progress; and
3. Produce progress reports twice a year including annual report to be submitted to the senior authorities of Ministry of Public Health.

12.2. Outcome and Impact evaluation

The NMFB together with relevant GoA/MoPH departments will conduct a mid-term review (MTR), 2014 and an end-term evaluation (ETE), 2016 of the Strategy. The MTR and ETE will provide feedback on the efficiency, effectiveness and relevance of the Strategy in achieving the strategic objectives. The report of findings and recommendations of the MTR will be widely shared with all stakeholders and used to modify outputs as may be necessary. The outcome of the ETE will be used to design and inform future interventions.

12. Resource Mobilisation

The key to successful implementation of this Strategy is availability of resources: financial, technical, human. Technical support will continue to be sort from partners such as SPS, WHO, FAO and others when required. The NMFB will advocate for increased budgetary allocations for medicine & food regulatory activities from the government, and mobilise additional resources from current and potential partners.

This strategic framework was prepared by the National Medicines and Food Board (NMFB) of the Ministry of Public Health with the financial support of US Agency for International Development (USAID) and technical assistance of Strengthening Pharmaceutical Systems (SPS), and do not reflect the views of USAID or the United States Government.

About SPS

The Strengthening Pharmaceutical Systems (SPS) Associate Award 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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