

## **Strengthening regulatory system and structure for Medicines and Food Products in Afghanistan: The way forward**

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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

ANSA	Afghanistan Norms and Standards Agency
DAI	Development Alternatives, Inc.
EDL	Essential Drugs List
FDQCL	Food and Drug Quality Control laboratory
GDPA	General Directorate of Pharmaceutical Affairs
GMP	Good manufacturing practice
GoA	Government of Afghanistan
HACCP	Hazard analysis critical control points
LDL	Licensed Drug List
MAIL	Ministry of Agriculture, Irrigation and Livestock
MoCI	Ministry of Commerce
MoJ	Ministry of Justice
MoPH	Ministry of Public Health
MoU	Memorandum of understanding
MSH	Management Sciences for Health
NMFB	National Medicine and Food Board
QA	Quality Assurance
QC	Quality Control
SPS	Strengthening Pharmaceutical Systems
TAFA	Trade and Accession Facilitation for Afghanistan
TLC	Thin Layer Chromatography
TOR	Terms of Reference
USAID	United States Agency for International Development
WHO	World Health Organization



## EXECUTIVE SUMMARY

The MoPH established the National Medicines and Food Board (NMFB) in 2009, as a multidisciplinary body to oversee and catalyze regulatory activities in medicines and food products. The NMFB itself would not have a direct regulatory function; but expected to provide guidance on the technical aspects of regulating medicines and processed food products; however, due to the lack of access to technical expertise and poor coordination among relevant departments, the board has been unable to fulfill its expected role.

In the same year, 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.

Responding to the request of MoPH, an initial assessment was conducted in March 2010 to understand the regulatory system and structure for medicines and food products in Afghanistan. Subsequent to the assessment, 3 options were identified and proposed to NMFB and MoPH for consideration in establishing a regulatory framework for the country.

The NMFB Task Force was established in January 2011 with the mandate to review the three proposed options that were discussed in the assessment report on establishing a Food and Drugs Authority, namely:

1. Strengthen the capacity of the NMFB ;
2. Strengthen the existing infrastructure and leverage resources that can be shared in medicine and food product regulatory activities ;
3. Establish an independent Afghanistan Food and Drug Administration.

The Task Force aimed to identify the option that is most feasible, sustainable and adaptable to the current situation and recommended in February 2011 the following option:

1. Strengthening the NMFB to play an oversight, coordination and advisory role for the regulation of food and medicines;
2. Establish a secretariat to provide administrative and technical support to the board ;
3. Strengthening the existing structures responsible for implementation of regulation functions.

The selected option and subsequent recommendations reflects the need to implement changes that are viable in the short and medium term.

The proposed Action Plan to implement the recommendations deals with the NMFB capacity strengthening and improvement of effectiveness and efficiency of medicines and food regulatory functions.

The Action plan to strengthen the NMFB capacity includes:

1. Redefine the NMFB ToR (as a policy advisory and oversight body);
2. Establish a secretariat and define its roles and responsibilities;
1. Orientation of NMFB on:
  - a) redefined ToR,
  - b) updated information on the current regulatory system for medicines and food products,
  - c) Introduction of duties, roles and responsibilities for different stakeholders in the board.

The Action plan to improve the effectiveness and efficiency of medicines and food regulatory functions include, but are not limited to:

1. Draft or update legislation;
2. Defining lines of accountability;
3. Implement documentation, record keeping, reporting and follow up activities;
4. Develop tools (registered medicines database, operating procedures, manuals, guidelines, etc.);

5. Increase effectiveness of medicine law implementation;

6. Short, medium and long term objectives and indicators were developed.

The chosen option was successfully reported and approved by the Deputy Minister of MoPH and NMFB members in March 2011. The NMFB approved the Task Force recommendations and the plan of action to implement the recommendations.

## BACKGROUND

### Afghan Regulatory System

The Islamic Republic of Afghanistan has a total area of approximately 250,000 sq mi (647,500 sq km) with a population (2008 est.) of 23,738,376<sup>1</sup>. 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. There is both public and private sector involvement in provision of health care services. All medicines that can be imported and sold in Afghanistan are controlled by the Licensed Drug List (LDL) which was first published in 2005 and revised in 2007. Medicines for use in public health facilities are determined by the National Essential Drugs List (EDL) which was first published in 2003 and revised in 2007. There is very little local pharmaceutical production and hence most medicines used in the country are imported from neighboring countries. Despite the existence of the LDL to control imports, the pharmaceutical market is chaotic with products coming through many different sources.

The General Directorate of Pharmaceutical Affairs (GDPA) within the MoPH is largely involved in the regulatory activities for pharmaceuticals amongst other responsibilities. The regulation of medicines is enshrined in the Medicine Law which was established in 2003 and its accompanying regulations. The government of Afghanistan does not have a law that described food control activities and the responsible agencies and their terms of reference. It is understood that the MoPH is responsible for the control of processed food and the Ministry of Agriculture Irrigation and Livestock (MAIL) is responsible for raw or unprocessed food. Quality control testing for both food and medicines is the responsibility of the Food and Drug Quality Control Laboratory (FDQCL) within MoPH. The regulatory system is generally considered to be weak with most of the activities in the private sector and to some extent in public sector largely uncontrolled. A recent QA survey reported 9% sub-standard medicines in both public and private sectors<sup>2</sup>. Apart from the structures within MoPH involved in regulatory activities, a National Medicine and Food Board (NMFB) was established as an advisory board to the MoPH. The board has oversight of some regulatory functions for both food and medicine but there is no permanent structure that could in its current state effectively support all of the required regulatory functions for Afghanistan.

## CURRENT MISSION

In 2009 the Government of Afghanistan (GoA) expressed its desire for assistance from Management Sciences for Health (MSH) / Strengthening Pharmaceutical Systems (SPS) for the establishment of a food and drug regulatory authority. SPS project, conducted an assessment of the regulatory system in April 2010.

At the conclusion of the April 2010 assessment visit, a report was drafted with three proposed options to improve the current regulatory system in the country: 1) strengthen the NMFB board, 2) support existing regulatory entities within MoPH while establishing one enforcement agency for both medicines and processed food products and 3) establish an independent Afghanistan food and drug regulatory administration (AFFDA).

The current activity is not an assessment of the regulatory system of Afghanistan but follow-up to previous assessment conducted in April 2010. This mission purpose is to present the April 2010

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<sup>1</sup> <http://www.infoplease.com/ipa/A0107264.html>

<sup>2</sup> Inua Yusuf, O. Zafar Mohammad, K. Wahid, F. Zakeria, D. Lee, T. Layloff, and M. Morris. October 2010. Afghanistan Medicines Sampling and Testing – A Quantitative Survey. Submitted to the USAID by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

assessment report, and to engage government ministries in a consensus building process to identify an option that is feasible and sustainable to the country context, as well as to lay out the strategies and action plan in implementing the necessary components for a functional regulatory framework.

## **APPROACH TAKEN TO THE CONSENSUS BUILDING PROCESS**

The Minister of Public Health assigned a Task Force within NMFB to review the proposed options and identify one that is most feasible, sustainable and adaptable to fit the current Afghanistan context.

A series of meetings were held with the Task Force and NMFB:

1. First meeting with the Task Force was to review and agree on proposed option based on the assessment report.
2. Second meeting with the Task Force was held to lay out the Strategic approach to implement identified option.
3. Third meeting with the NMFB was presenting the selected option, an action plan and the next steps.

In addition to the meetings with the Task Force and NMFB, a series of meetings with the relevant stakeholders were conducted, to supplement the findings that were not adequately assessed in the previous assessment report. Based on these findings, a comprehensive mapping of the regulatory functions and activities carried out in the country was done, and this allowed for specific recommendations in the action plan.

The following report describes the additional findings and analysis done during this mission, and summarizes the action plans, next steps and implementation strategy to strengthen the regulatory system in Afghanistan.

## **MISSION FINDINGS:**

### **Organizational structure**

#### **Medicinal products:**

Structurally, the present drug regulatory system in Afghanistan differs in various respects from corresponding systems that have proved successful in many other countries. The mission had the impression that the present system reflects in various respects the disturbed state of governance in Afghanistan during recent decades, prior to which an excellent drug regulatory system existed. Since then, in this as in some other fields, a considerable degree of improvisation has proved necessary. This has been of value, but has resulted in a system that in the long run will need to be replaced. The fact for example that "registration" and "procurement" are handled by a single unit (now known as the registration and licensing department) reflects the current situation of heavy donor dependence; with a future move back to a more normal market situation, the issues of licensing and of procurement, that require entirely different forms of operation and expertise, will need to be strictly separated.

The system is fragmented, with complex lines of authority, accountability, coordination and reporting among various departments involved in regulatory activities within GDPA in the MoPH. This is not conducive to smooth and efficient operation and may in part explain why the system fails to deal with a number of issues of public health importance that in many countries are regarded as essential topics for national policy and regulation.

The following section illustrates the mapping of the current regulatory functions, with their corresponding departments and ministries.

## Mapping of the current regulatory functions

The mapping of the current regulatory system was done focusing on the main regulatory functions as defined by World Health Organization (WHO)<sup>3</sup>. The main regulatory functions that were looked at are licensing of premises, registration of medicines, control of import and exports, inspections and enforcement, quality control, post marketing surveillance, control of advertising and promotion and control of clinical trials.

Responsibilities for performing regulatory functions is scattered in various departments mainly in the GDPA and some functions are in other departments within the MoPH. To note also is that some functions although assigned to specific departments according to the terms of reference – these functions were not implemented. Summary of the distribution of regulatory activities is presented in table 1 below.

**Table 1: Current state – responsibilities for performing regulatory functions**

<b>Regulatory function</b>	<b>GDPA</b>	<b>Other departments/institutions</b>
<i>Licensing of premises:</i>		
1. Manufacturers	Pharmacy Technical Board	Some cases referred to NMFB
2. Wholesalers and importers	Pharmaceutical Establishment → Department of distribution of medicines	Some cases referred to NMFB
3. Pharmacies	Pharmaceutical Establishment → Department of distribution of medicines → Private pharmacy establishment	Some cases referred to NMFB
Renewal/post license approvals - change of technical personnel in pharmacies	None	Legislation Implementation and Ensuring department
Control of imports and exports	Pharmaceutical Procurement and Registration Pharmaceutical Supervision and Evaluation department	Provincial Public Health Directorates (for sample collections)
Inspection/enforcement -GMP inspections	GMP – Pharmaceutical Supervision and Evaluation (non functional)	Private pharmacies – Legislation Implementation and ensuring directorate
-Routine inspections – other premises	Wholesalers, pharmacies & importers – Pharmaceutical Supervision and Evaluation Department.	
Registration of medicines – foreign manufactured medicines	Registration of manufacturer and product within Pharmaceutical Procurement and Registration	None

<sup>3</sup> Ratanawijitrasin Sauwakon and Eshetu Wondemagegnehu, Effective drug regulation: A multi-country study. World Health Organization, 2002, Geneva, Switzerland

<b>Regulatory function</b>	<b>GDPA</b>	<b>Other departments/institutions</b>
	Department	
Registration of medicines – local manufactured medicines	Pharmacy Technical Board	None
Quality control	None	Food and Drug Quality Control Authority Environmental Health department (processed food)
<i>Post market surveillance:</i>		
1. Quality control post registration	Pharmaceutical Supervision and Evaluation department	Food and Drug Quality Control Authority
2. Product recalls and defects	None	None
3. Adverse drug reactions	Avicenna Pharmaceutical Institute ( <i>non functional</i> )	None
Control of clinical trials (regulatory and ethical oversight)	Avicenna Pharmaceutical Institute ( <i>non functional</i> )	None
Control of promotion and advertising	None	None

The diagram depicting the regulatory functions and their corresponding ministries / departments is in Appendix II.

### **Food products:**

Similar to the medicinal products, the system regulating food products is fragmented and poorly coordinated. Ministries involved in the regulatory affairs of food products are: Ministry of Public Health (MoPH), Ministry of Agriculture, Irrigation, and Livestock (MAIL), Afghanistan Norm and Standard Agency (ANSA), Ministry of Commerce (MoCI).

Afghanistan is primarily focusing on inspection and testing of the end products. Inspection of the physical establishments is also done by multiple departments and ministries. As for other components in food safety, such as food control management, product tracing, it is not known whether or not any government departments / agencies are involved in it.

**Table 2: Current state – responsibilities for performing regulatory functions**

<b>Regulatory function</b>	<b>MoPH</b>	<b>Other departments/institutions</b>
<b>Food Inspection</b>	Environmental Health Department Legislation, Implementation, and Ensuring Department Monitoring and Evaluation Department	None
<b>Quality control</b> (Sample testing)	Food and Drug Quality Control Lab	Plant and Veterinary Divisions Food Quality Department of Ministry of Agriculture, Irrigation and Livestock (MAIL)
<b>Licensing</b> (of premises)	Environmental Health Department	None

The organogram depicting the regulatory functions and their corresponding ministries / departments is in Appendix III

## Legislation

### Medicinal Products:

The current legislation, Medicine Law 2003, includes the main regulatory areas to be regulated. Areas covered by the law but not being implemented include licensing of all medicines manufactured, imported or offered for sale in Afghanistan, advertising and promotion and the control of clinical trials. Some activities are done to a limited extent such as classification of medicines. There is variance in what the Law states and what is actually being implemented. For example, all licenses according to the Law have a period of validity but this is not being enforced. Licenses issued have a validity period e.g. 5 years for pharmacies according to the Law, but renewal systems are not being implemented. In some cases, the actual responsibility as stated in the Law is not in-line with current status. For example, issuing of product licenses is based upon review of application by National Medicines Agency within Avicenna Pharmaceutical Institute – this is non functional and currently department of Procurement and Registration is responsible for registering manufacturers. Issuance of importation and wholesale licenses are combined in the regulations, however, currently import and wholesaling licenses are issued separately. Law mentions inspection of pharmacy premises without mentioning the specifications of the physical and structural requirements, this leaves gaps which are open for various interpretation.

In some cases, insufficient provisions are made in the legislation which leaves gaps in terms of implementation. For example, there are no adequate provisions on non-compliance with the law. The law only mentions that the "*offender shall be subject to penal process*". This is not clear whether the "penal process" for each offence is defined elsewhere. Law mentions licensed seller as requirement for other type of pharmacies, but does not provide clarity on this type of cadre and how they are licensed. No provisions set for penalties and administrative measures except that these will be set by Minister of Public Health and Minister of Justice. No provisions in the law for inspections, designating inspectors and power of inspectors such as to enter premises, conduct searches and confiscate unlawful medicines. Some regulations exist on some functions mentioned in the law. However, some activities or regulatory functions have no regulations in existence based on information available during the mission. Any appeals on licenses are to be made to Minister of Public Health.

In general, lack of transparency and gaps result in misinterpretations and potential manipulations in the regulatory process. There is no provision in law to communicate with public on any regulatory information or updates. Lack of public access on regulations and standards can promote corruption. In some cases, where the law may be considered adequate, there is lack of implementation of regulatory functions.

The general scheme of Legal Structures and Procedures on Afghan models and future drafting needs in the medicines fields are in Appendix I.

### Food products:

Currently there exists no food law in Afghanistan that describes the food control activities, the responsible agencies and their terms of reference, nor do the respective ministries have specific legislation in place for the control of food. However, Trade and Accession Facilitation for Afghanistan (TAF) is working on draft Food Safety Law model and once completed, it will share with all relevant stakeholders. Ministry of Agriculture, Irrigation, and Livestock (MAIL) have draft legislation which is waiting to be formally enacted. This legislation specifically covers Animal and Veterinary Public Health issues but does not currently encompass all the attributes of a Food Control System, particularly with regard to using preventative food safety approaches. The National Standard Law exempts food processing and meat processing establishments from regulatory oversight.

## **Distribution of responsibilities, duties and powers**

### **Medicinal products:**

Based on the assessment reports and information gathered during the mission, responsibility on some regulatory functions is not very clear amongst the various departments with areas of overlap e.g. several departments involved in the inspections such as Legislation Implementation Ensuring Directorate (LIED), Supervision and Evaluation Department within GDPA, Provincial Health Directorates and the Monitoring and Evaluation Directorate. There is need to ensure that responsibilities, duties and powers are covered in the law and alignment of terms of reference, the law with actual activities on the ground. SPS is currently performing a functional analysis of the GDPA. This is a good starting point to define the responsibilities, duties and powers of each department. However, there is need to include other departments outside GDPA involved in regulatory activities to cover the whole regulatory system for medicines and food. The Pharmacy Technical Board within GDPA is highest decision making authority within GDPA. However, scope of work for the technical Board is very limited as it only deals with borderline issues i.e. unusual cases and approval of applications for medicine imports. Its composition includes pharmacists from the GDPA and 2 lecturers from Department of pharmacy and pharmacology from Kabul University.

The current structure for regulation of medicines and for food is presented as appendix II. It is apparent that there is no clear structural and functional linkages between various bodies involved in drug regulation. Since the regulatory functions are within MoPH structure, a system for monitoring and evaluation exists. There is a directorate of Monitoring and Evaluation whose role is monitoring performance of all departments within MoPH including regulatory activities. However, it appears there are no clear lines of roles and responsibilities as the directorate is also involved in inspections of establishments and joint inspections with GDPA in some cases.

### **Food products:**

Currently Afghanistan has a food control system that uses multiple agencies, principally MAIL and the MoPH with provincial health departments, ANSA, the MoCI who issue export certificates and possibly also other agencies in the provinces. Other actors that are involved in food control activities in Afghanistan are MoF, Customs department and University of Kabul, Faculty of Pharmacy. Lack of clarity of the different agencies responsibility with duplications on regulatory activity, fragmented surveillance and lack of co-ordination are problems in food area. Due to this lack of definition, duplication, authority conflicts and gaps have been observed.

Appendix III organogram ministries and departments regulatory functions shows duplications between relevant ministries and departments, particularly the MAIL and MoPH, and within departments, for example between the Meat and Plant Divisions and the Food and Quality Control Department.

## **Financing**

### **Medicinal products:**

There is no autonomy (financial and recruitment of staff) within the regulatory structures since they are not independent. Financing of the regulatory activities is 100% supported by the government. It is not clear if the MoPH has a specific budget for drug regulation, but this is highly unlikely as functions are distributed throughout MoPH with same departments involved in other non-regulatory activities. From the assessment report and meetings with various departments, there are limited resources given the current economic situation in Afghanistan. This means funding for regulatory activities among other priorities for the government will be affected by resources available to the government. Sustainability of the current or

any system to be supported by the donors will largely depend on the economic development of the country.

The law makes provision for charging fees for regulatory activities, such as licensing fees for establishment, registration fees, approval of import pro-forma. However, the collected funds are remitted to Ministry of Finance. The collecting departments have no control over the use of the collected revenues. In addition, it is not inconceivable that the government of Afghanistan is also subsidizing the private sector as some of the fees are not realistic for the service provided. For example, for each application for 'registration' of new product for a registered manufacturer costs US\$100. This is very low compared to the actual work for registration of a product and also comparing to other countries.

### **Food products:**

This is not assessed during this mission.

## **Availability, clarity and transparency of procedures and guidelines**

### **Medicinal products:**

There are inadequate documentations and record keeping processes for all regulatory activities. The information is available is not easily accessible and not shared with other interested departments. Discussions with private sector revealed lack of awareness of what tools and information is available. For example, they were not aware of any classification system for medicines or the process for applying for addition of products to the LDL. However, the information is available only at the back of copy of the LDL. No efforts are made to publish as wide as possible regulatory decisions, or distributing available documents to interested parties such as the list of products added to LDL. Such information is only available upon request.

Not all procedures have guidelines, manuals or standard operating procedures. If available, the guidelines or procedures are not comprehensive enough to allow for effective and transparent regulatory processes and decision making. Most procedures and decisions are not written down and hence there is no traceability. Proper record keeping system was absent – for example, list of registered manufacturers was not up to date and informative, list of licensed premises was not available and list of licensed medicines could not be obtained from GDPA.

Most decision making is done internally except for few cases referred to multi-stakeholder NMFB. For transparency in decision making, there is need for independent committees such as approval of applications for registration of medicines.

Based on meeting notes from the FDQCL, the proportion of medicines failing QC testing was very low compared to recent QC reports done by other organizations which reported at least 11% and 8% sub-standard medicines from public and private sector respectively<sup>4</sup>. Another study by John Hopkins University in Basic Package of Health Services (BPHS) facilities in 2007 revealed prevalence of 4% sub-standard medicines<sup>5</sup>. This casts a lot of doubt on the validity of the results from the FDQCL given the several challenges faced by the laboratory.

### **Food products:**

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<sup>4</sup> Inua Yusuf, O. Zafar Mohammad, K. Wahid, F. Zakeria, D. Lee, T. Layloff, and M. Morris. October 2010. Afghanistan Medicines Sampling and Testing – A Quantitative Survey. Submitted to the USAID by the Strengthening Pharmaceutical Systems (SPS) Program. Arlington, VA: Management Sciences for Health.

<sup>5</sup> Afghanistan National Drug Quality Assessment Study, 2007, Ministry of Public Health in Collaboration with John Hopkins University Bloomberg School of Public Health and Indian Institute of Health Management Research

Currently there are no standards in place for foods, its processing and storage of distribution. A few local producers have put the either Hazard Analysis Critical Control Point (HACCP) or a different quality assurance system in place, however, there is no government agency that oversees the implementation of either voluntary or mandatory quality assurance in food production.

Currently, TAFE is working actively on several regulations, guidelines SOP's and awareness documents, for example:

1. HACCP general information pamphlet to raise awareness about HACCP and to help facilitate implementation.
2. Regulation for good manufacturing practice in manufacturing, packing, or holding human food;
3. Afghan Regulation for Sanitation Standard Operating Procedures;
4. Afghan Regulation for HACCP Systems.

## **Processes**

### **Medicinal Products:**

The development of Afghan regulatory system has evolved in a random manner due to the 3 decades of war. From the information gathered, it appears some functions being performed have evolved from public sector and directly applied to private sector without adjusting to the context. The existing structure and some problems noted are due to this structural and functional system which was designed not on regulatory perspective but procurement system for the public sector. The quality assurance system in place is a testimony to that. For instance, procurement and registration is one department (*this has since been changed*). The specific activities of the department include 'registration' of medicines when in actual fact the department registers manufactures and not specific medicines. Once a manufacturer is registered, any product from such a manufacturer can be imported into the country. This is different from the normal registration system in terms of drug regulation which requires each specific product to go through a registration process and maintenance of a registered list of medicines that can be imported or used in the country. In summary, the control of medicine importation and use is largely based on licensed drug list and registration of manufacturers. This makes it nearly impossible to regulate the products available on the market.

In some cases the process of seeking approval is unnecessarily long with applications having to go through the Minister of Public Health. In some cases it is the criteria for the involvement of the NMFB board is not very clear and whether the board has the technical capacity to make decisions on technical issues is questionable given the composition of the board. Annex 2 has the process flow diagrams for some of the regulatory functions.

### **Food Products:**

This is not assessed during this mission.

## **IDENTIFIED CHALLENGES AND LIMITATIONS**

The country has remained too isolated from international developments in this field and from the relevant literature, combining the lack of access to technical knowledge, brain drain on human resources and limited funding support, compilation of these factors contributed to the formation of an ill-functioned regulatory structure and system.

Following were observed during this mission:

1. The duties and responsibilities of the NMFB are very limited in scope. (ref QA assessment report)

2. There are no or inadequate tools such as guidelines, SOPs for regulatory functions i.e. registration of medicines, licensing etc
3. Processes for performing regulatory functions are not efficient and maximizing the available resources
4. Lack of capacity of the FDQCL lab for testing of medicines and food
5. Porous borders which makes it difficult to control importation of medicines
6. An inadequate record keeping process which makes accessibility of information very difficult e.g. list of licensed establishments, registered medicines.
7. Some framework is present but challenge is implementation of this regulations. Partly due to interference by companies and politicians
8. Lack of knowledge and understanding of the law by the implementers as some regulations not applied correctly.
9. Corruption – lack of transparency and good governance

### **GENERAL RECOMMENDATIONS:**

Given the fact that most elements in the regulatory structure are either ill-functioned or absent in Afghanistan, it is seriously doubtful that establishing single regulatory agency to handle both drugs and foods is the solution to address multitude of challenges and issues facing the country today. It is true that in some countries (ranging from the U.S. to Indonesia) joint agencies handling both of these fields exist, but because the expertise, policies and facilities required to handle foods and drugs are different, the two fields are even in these joint agencies largely dealt with separately. Joint action can be required for borderline areas (e.g. vitamin products, health food claims) but this can be handled by arrangements for consultation. There is also a market reluctance to make any drastic change at present in the current system such as might derange its function. Its deficiencies can better be dealt with at present by incremental adjustment. At a later stage, if donor dependence becomes less and a more normal market situation supervenes, a fundamental redesign of the system can be considered.

Having said that, it is recommended to strengthen the regulatory system in a step-wise manner, this should be preceded in two distinct phases. Firstly, it should consider progressive introduction of selected improvements to the current system so that it can continue for a number of years to serve the public interest so long as heavy donor dependence continues. This can be fulfilled by strengthening the capacity of NFMB to play an oversight role to supervise these modifications and avoid serious derangement to the system, and to establish a secretariat office within NMFB to render technical support for advisory, coordination and facilitation.

Secondly, a new system of drug policy and regulation can be designed, referencing the best model or structure from other countries, for introduction in Afghanistan that is in line with social economic progress.

### **Strengthening the NMFB board**

- 1) Redefine the NMFB Terms of Reference (ToR)
- 2) Establish a Secretariat and define its roles and responsibilities
- 3) Orientation to NMFB on:
  - a. Redefined ToR
  - b. Updated information on regulatory system for medicines and food products
  - c. Introduction of duties, roles and responsibilities for different stakeholders in the board

Complement to strengthen the NMFB board; the following components also need to be strengthened to comprehensively address the deficiencies in the system.

### **Strengthening the existing structures**

1. Draft legislation for food
2. Update legislation for medicines
3. Define lines of accountability
4. Implement documentation, recording keeping, reporting and follow-up activities
5. Develop tools (registered medicines database, operating procedures, manuals, guidelines, etc.)
6. Increase effectiveness of medicine law implementation
7. Develop and implement a medicine registration system/ process

To monitor performance of the above components, short, medium and long term objectives and indicators were developed (Appendix IV).

## **SPECIFIC RECOMMENDATIONS:**

### **Medicinal products**

#### **Documentations:**

An important part of NMFb's task is to document in concrete terms the need for certain priorities, documenting in as concrete a manner as possible the reasons (e.g. in terms of the economy and of public health) which demand that action be taken, and this record keeping should be readily accessible and traceable.

Externally, the information on registered importers, medicines, manufacturers, wholesalers, pharmacies, decisions to applicants, should be easily accessible by the public. Tools such as, guidelines, SOPs, should also be readily retrievable and easily accessible by the public. These can be done by maintaining a manual, electronic databases and or internet website.

#### **Funding mechanism for medicines control:**

A decision of principle needs to be made as in what form and manner that a new regime for medicines control is to be funded. One suggestion is a "fee-based" system to finance in full the processes of control, approval and inspection. It is feasible to calculate in economic terms the benefit to the community resulting from the implementation of firm policies in this field and thereby to gain political and community support for a fee-funded system. That benefit will flow in part from the savings when the Treasury is no longer required to fund the present regulatory system and in part from the wastage that results from the sale and use of unapproved items. The revenue in the pharmaceutical field can be extensive and profitable that substantial fees can be levied both on professionals and traders. Trade and industry may initially object, but reputable firms welcome the establishment of a well-funded and efficient system and gladly pay whatever fees prove necessary to ensure its creation and maintenance, especially because such a system removes inferior firms from the market.

#### **Engagement of consumer / public interest:**

To counterbalance the interest of private sectors or industry, and to lessen their pressure exerted on government, means of developing a broad consumer involvement need to be considered, specifically to advocate / voice concerns / interest on behalf of the general public, on issues such as accessibility, availability and pricing of medicines. The initial step to this initiative could be to publicize the essential elements of the country's national drug policy and the benefits that it could bring.

#### **Roles, responsibilities and authorities**

As previously mentioned, while the concept of a single regulatory authority handling both foods and drugs has been applied in a small number of countries, it has to be recognized that the two fields are in many respects different as regards procedures, priorities and the type of expertise required. In principle they can better be dealt with separately, though on a certain number of issues they overlap and here some joint action may be necessary (notably with products that have characteristics both of foods and of drugs (e.g. vitamin preparations).

Having said that, there is a need to clarify the roles, responsibilities and involvement on the regulatory functions for food products between the Ministry of Public Health and Ministry of Agriculture, Irrigation and Livestock (MAIL).

#### **Legislation – medicines**

The medicine policy as currently presented does not follow the WHO's recommended format, which provides for specific policy direction lines for medicines quality assurance. A review of the policy and the development of an accompanying national pharmaceutical master plan are therefore needed.

There should be a comprehensive Law and regulations for all regulatory functions.

The medicines law covers product registration, pharmaceutical establishment licensing, control of medicine importation, inspection services, monitoring for quality and adverse drug reactions, control of medicine promotion and advertising, and medicine quality testing/control. The law already has provision for most of the regulatory functions including the NMFB. What is required is to revisit the functions that each is going to play and then see if the law needs updating to reflect such changes i.e. revisit the duties and responsibilities of the NMFB.

Law makes provision for most of the regulatory functions including pharmacovigilance, control of advertising and promotion. Efforts should be made on the implementation of the law. Focus and emphasis should be capacity building of relevant institutions to implement these functions.

### **Strengthening GDPA capacity – leveraging existing structure and resources**

GDPA is the primary department responsible in executing the regulatory functions in medicinal products. Based on interview and document review, the GDPA has an internal technical board in place. Its composition is defined in QA assessment report. This technical board can be strengthened and utilized to discharge the mandate of GDPA for all regulatory functions that fall under GDPA where necessary. This will ensure transparency and good governance in regulatory decisions. For the reporting mechanism, the GDPA technical board's responsibilities are to evaluate the cost of imported medicines, medicines production, and importation, and identify medicine-related problems for submission to the NMFB. In light of the new proposed option for regulatory framework, this reporting mechanism can be strengthened and utilized for all regulatory activities. Proposed framework include reporting to NMFB from GDPA and system is already in existence no further drastic changes necessary.

### **Registration and licensing**

*There should be a reasonable / efficient process for receipt and processing of all applications i.e. for registration of manufacturer, registration of importers, import licenses, registration of medicines*  
Some system of medicine registration or licensing is already in place, therefore, building a registration system can be done based on what is current there and some of the tools that have already been developed such as licensed medicines list. For license issuance, it is suggested to establish a renewal system as opposed to the current open ended licenses.

## **Food products**

### **Food control management**

Effective food control systems require coordination of policy and operations, as well as specific task fulfillment, at the national level. This process includes establishment of a coordination entity or a single body (such as: food products committee under NMFB) and creation or reorganisation of existing control authorities with clearly defined accountability for such issues as:

1. development and implementation of integrated national food control strategy;
2. operation of a national food control programme;
3. securing funds and allocating resources;
4. setting standards and regulations;
5. participation in international food control related activities;
6. developing emergency response procedures;
7. carrying out risk analysis, etc.

Core responsibilities of a coordination entity or single body (such as: food products committee under NMFB) include:

1. establishment of regulatory measures;
2. facilitating continuous improvement; and
3. providing overall policy guidance

## **Legislation – food products**

The development of relevant and enforceable food laws and regulations is one of the essential components of modern food control system. To the extent possible, modern food laws not only contain necessary powers and prescriptions to ensure food safety, but also allow the competent authorities to build preventive approaches at all stages of the food chain.

In addition to food laws, Governments need to have updated food standards. They should take full advantage of Codex Alimentarius standards, guidelines and recommendations, as well as food safety experiences of other countries. They should tailor the information, concepts and requirements to the national context in order to develop a modern regulatory framework that will both satisfy national needs and meet international obligations and requirements of trading partners.

Effectiveness of official controls and management activities carried out by business operators to ensure food safety depends upon the applicability of food law.

## **Food inspection**

While the responsibility for providing consumers with safe food rests with all parties engaged in producing, processing and trade at all stages of the food chain, official control services are responsible for enforcement of food safety law. Inspecting food, premises and processes, they prevent the sale of hazardous food.

The food inspector is the key functionary who has day-to-day contact with the food industry, trade and often the public. This requires competence, qualification and honesty.

Due to the trend in modern food control systems away from withdrawing unsafe food and punishing parties responsible when problems occur to applying preventive approach, producers and traders must develop and introduce management based on principles of Hazard Analysis Critical Control Point System (HACCP) according to their potential, experience and resources. This forces food inspectors to facilitate introduction of HACCP systems and conduct risk-based audit.

Functions of official food control services also include inspecting, sampling and certification of food for import/export control purposes.

## **Food safety system**

There is need for a number of administrative measures to be established by law and steadily taken in order to ensure the acceptability, effectiveness and efficiency of the national food control system.

Along recommendations for the regulatory system, the recommendations listed below relates to some aspects of food inspection as it needs to be urgently revised:

1. Re-establish and review memorandum of understanding (MoU) between MoPH and MAIL;
2. National policies should be established for the three food supply streams (domestic, export and import) using a "Risk Based" approach to tackling the issues;

3. The current sampling programmes used by the regulatory agencies need to be fully reviewed and project decisions made on risk based food inspection and sampling programmes, including imported food control. Imported food monitoring and risk analysis shall cover all relevant information depending on type of product, country of origin, number of consignments, previous history of testing results, history of importer, available resources;
4. Samples must be delivered directly to the FDQCL, where tests are carried out;
5. Establish proper food establishment licensing arrangements, which include pre-inspection of food premises.

### **Official food control laboratories**

It is essential that effective linkages are established between laboratories and other elements of the national food control system. In this way information on foodborne diseases may be linked with food monitoring data, and lead to the development of appropriate risk-based food control strategy.

### **Food safety and quality and IEC (Information, education and communication)**

An increasingly important task for food control systems is the delivery of information and advice to stakeholders at all stages of the food chain – from farm to table. These activities include:

1. provision of balanced factual information to consumers;
2. provision of information and educational programmes to key officials and employees in the food industry;
3. development of train-the-trainer programmes;
4. provision of reference literature to extension workers

### **Traceability**

The food chain often involves many steps, from the import or primary production of a product to its sale to the final consumer.

Traceability is a risk-management tool which allows food business operators or authorities to withdraw or recall products which have been identified as unsafe.

Codex Alimentarius uses the following definition<sup>6</sup>:

Traceability/product tracing<sup>7</sup>: the ability to follow the movement of a food through specified stage(s) of production, processing and distribution

Traceability/product tracing is a tool for competent authorities within their food inspection and certification system that may be applied, when and as appropriate, within a food inspection and certification system in order to contribute to the protection of consumers against food-borne hazards and deceptive marketing practices and the facilitation of trade on the basis of accurate product description.

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<sup>6</sup> Principles for traceability / product tracing as a tool within a food inspection and certification system CAC/GL 60-2006.

<sup>7</sup> Codex Procedural Manual

## **PRIORITY SETTING/INTERVENTION**

Given the political and socioeconomic environment, existing fragmented regulatory structures, limited human and financial resources, and the level of development of the pharmaceutical sector in the country, it is not practical to implement all the proposed changes at once. Therefore, it is important to set priorities in implementing specific regulatory functions or activities that will achieve the most desired results in terms of public health i.e. quality, safe and effective medicines. Implementation will then proceed in a stepwise or phased manner as the pharmaceutical sector develops and more resources – human and financial become more available and the country’s economic situation improves.

## **NEXT STEPS**

The following next steps were agreed and approved by the NMFB and MoPH:

Strengthen the NMFB:

### **1. Redefine the NMFB Terms of Reference (ToR)**

Begin by developing the process for establishing the revised ToR, present this developing process to the NMFB for review and approval. Establish a ToR framework, and solicit stakeholders input through a stakeholder’s forum. Draft the ToR based on the input, circulating the draft to stakeholders for review, finalize, and approval.

A re-orientation of the NMFB with the redefined ToR will then be held to re-introduce all relevant stakeholders about the roles, responsibilities and expectations of the NMFB; responsible government ministries and departments involved in the regulatory functions will also present to brief their duties, roles and responsibilities.

### **2. Establish a Secretariat office:**

As part of the interventions to strengthen the NMFB, a secretariat office with technical and administrative staff will be created to support NMFB. Their primary responsibilities will be to assist in ensuring that the NMFB board and other stakeholders involved in pharmaceutical and food products regulatory functions are better coordinated and function effectively to ensure quality, safety and efficacy of pharmaceutical and food products in Afghanistan. The Technical Officer(s) will provide technical assistance to the board to ensure that it discharges its mandate of overseeing the performance of the medicine and food regulatory system and providing advice and recommendations for action to the Minister of Public Health.

## APPENDIX I : FUTURE DRAFTING NEEDS IN THE MEDICINES FIELD.

In order to make progress in the law and regulation of medicines, three types of initiative will be needed. *Firstly*, various legal and regulatory provisions which have been formally accepted but not in fact implemented (or incompletely implemented) in practice will need to be activated so that they take effect. *Secondly*, some existing laws and regulations will probably need to be amended or updated. *Thirdly*, there are many areas in which laws and regulations are completely lacking, and here they will have to be created.

These challenges are surveyed below.

Where new drafts are needed it will be possible to provide material at short notice, based on the best experience in other countries but naturally requiring modification to suit the needs of Afghanistan.

### A. THE OVERALL POLICY DOCUMENT

#### NATIONAL MEDICINE POLICY

*Principles:* Many countries have found it helpful to produce a declaration of the purpose, nature and components of the national policy on medicines. It is not a law creating rights and duties, but it provides guidance to those involved in drawing up more specific measures. It needs to be based on a firm consensus, and it may take the form of a published declaration by the president, the parliament or the Minister of Public Health, or it may be a resolution drawn up by a conference representing the authorities, the health professions, the trade and industry, and the public. It should be readily available, e.g. on the internet and in the form of a widely available booklet used for educational purposes and public information.

*Available material:* A six-page "National Medicine Policy" was drafted in English in the framework of the 2003 MSH consultancy. Successive sections deal with:

1. Definition and goals of medicine policy
2. Supply and control
3. Efficacy. Safety and quality
4. Advertising and Promotion
5. Information (and the creation of a Medicines Information Centre)
6. Accessibility
7. Lowering of Financial Barriers
8. Lowering of Financial Barriers
9. Involvement of the Health Professions and Community
10. Selection of Medicines (Lists of Essential Medicines, Free Sale Medicines and Restricted Medicines)

*Status:* The draft was positively received at the National Workshop on Drug Policies in March 2003 and had subsequently been translated and officially adopted, though it is not clear what procedure was followed; a "policy document" is not a law but a statement of intent and motivation, e.g. issued by a Government or Minister. The official Dari text was largely follows the MSH draft, but that there are some additions and omissions. The former are largely intended to provide the reader with explanation, and they are fully acceptable. Most of the omissions are simply intended to avoid duplication and are equally acceptable. There are no serious errors. *Bearing in mind that the existence of an "official" declaration of policy on medicines is a significant achievement it is suggested that no changes be proposed. It is more important that the existence of this policy document in its present form be publicized and made the subject of public education and debate, something that up to the present has been lacking.*

### B. FUNDAMENTAL LEGISLATION

## **B.1. THE LAW ON MEDICINES**

*Principles:* As a specific law, compatible with other specific laws in the field (see B.2. onwards) and with whatever general legislation on health is in force, a Law on Medicines must be formally passed by the legislature. It should lay down the fundamental principles, rights and duties applicable to the making, sale, distribution and use of medicines. Depending on national preferences it may or may not extend to vaccines, veterinary products and certain other types of goods, or these may be covered by separate laws.

*Available material:* A 20-page "Law on Medicines" for Afghanistan was drafted during the 2003 MSH Consultancy, it was then modified by GDPA and MoJ, Afghanistan Parliament approved it in 2006. While closely analogous to the Medicines Laws operating in any other countries it is for the sake of clarity more concise than most, relegating much detail to the regulations that need to be made under the law. Successive sections deal with:

1. Basic principles, purpose and definitions
2. Establishment of an Afghan National Formulary
3. Approval of new medicines and related products
4. Licensing of importers and wholesalers
5. Retail sale
6. Licensing of Manufacturers
7. Illegal possession
8. Donations of Medicines
9. Scheduling and classification
10. Rational Use
11. Advertising and Promotion
12. Pricing and Cost Containment
13. Adverse reactions
14. National Poisons Information Centre
15. Clinical Trials
16. Traditional and Complementary Medicines
17. Supplementary Measures
18. Financing and Fees
19. Sanctions
20. Monitoring
21. Transitional Provisions

*Status:* Based on the "Law on Medicines" drafted in 2003, GDPA in collaboration with Ministry of Justice modified the 20-page document; "Drug Law" was subsequently approved by the Parliament in November 2006.

This modified draft included the legal mandate for National Medicine Board, and in addition the articles:

Article 1: Basis

Article 2: Definitions

Article 3 – 4: members and mandate of NMB

Article 5 – 7: Updated ANF

Article 8 – 16: Manufacture and Importation of Medicines and Medical Equipment including: Issuance of License, Manufacture, importation and supply of medicines outside the licensed drugs list, License, drug procurement authority, importation and supply of medicines by NGOs, Importation of Medicines, supply of chemical substances, procurement of medicines utilized in special cases, and determine the selling prices of medicines

Article 17 – 27: Sale of Essential Medicines and Medical Equipment, including: Establishment of Pharmacy, License for Establishment of Pharmacy, Classification of a Pharmacy, License fee for Establishing a pharmacy, Sale and Ownership of a pharmacy, Sale of Drugs on Prescription, Storage and Transportation of Medicines, Receiving Authority of Donated Medicines, Prescription for Purchase of Medicines outside the hospital, Medicines are not allowed to be sold in Clinics, Working Procedure of Pharmacy.

Article 28 – 38: Rational Use of Medicines and Medical Supplies, including: Rational Use of Medicines, Unlicensed Medicines are not allowed to be dispensed, Writing a prescription, specification of prescription, assessment of prescription, Teaching the generic name of medicines, inclusion of basic concepts in syllabus, publishing the reaction report of medicines, advertising of medicines, administering medicines in human organ is prohibited, disposal of medicines.

Article 39 – 47: Punishment Provisions, including: financial punishment, suspension of importation license, manufacturing and importing of counterfeit medicines, sale of donated medicines, advertising, ceasing the activities of a pharmacy, closure and suspension, cash deposit, violating the provisions of regulation.

Article 48 – 49: miscellaneous provisions, including: drug inspectors, traditional medicines.

*Recommendation:*

With the subsequent modifications by the GDPA and Ministry of Justice, the updated version needs to be reviewed to assess its adequacy and comprehensiveness.

Again as in the case of the National Medicines Policy, the NFMB should form its own view on the current acceptability of this legal text and the possible need for revision and further approval by the legislature. Steps then need to be devised to implement the many sections of the law that have remained unimplemented, with a careful selection of priorities.

Note: Before the sections B2, B3 and B4 (below) can be finalized, more information is needed on the current law and regulation in these areas and the extent to which this has actually been implemented. Only a certain part of the general Law on Medical Practice is applicable to medicines

## **B.2. The Law on Pharmacy**

In Afghanistan, a Law on Pharmacy was passed in 2006 (18.10.1385), almost at the same time as the Law on Medicines and it is therefore likely to be compatible with the latter, but this point will need to be examined.

*Principles* A law on the pharmaceutical profession covers topics ranging from the education, specialization and licensing of professionals to the establishment, operation and inspection of retail pharmacies. In various respects it therefore needs to be strictly compatible with the Law on Medicines.

*Available material* During the MSH consultancy of 2003 a set of “Regulations on Pharmacies” was drawn up for the Workshop. Comparison must await translation of the Law.

*Status* Some serious but deficiencies in retail pharmacy practice are widely acknowledged. In particular, medicines subject to a prescription requirement are generally sold freely, unlicensed medicines are available and inspection is insufficient. Many of the pharmacists trained in Afghanistan prove to be employed in laboratory work (e.g. in hospitals) and a large proportion of retail pharmacies do not employ a professional pharmacist, finding it less costly to employ either a “compounder” (pharmacy technician with one year of training) or entirely unqualified staff.

*Recommendations*

The only enacted pharmacy law is the “retail pharmacy regulation” and is developed based on medicine law. Again, it needs to be reviewed to assess its adequacy and comprehensiveness.

The NMFB Task Force will be well advised to examine the existing Law on Pharmacy to determine to what extent it is adequate to deal with these and similar faults, and how these deficiencies can be remedied

despite the limited resources available. The MSH team, too, will formulate an opinion on its adequacy and advise the Task Force accordingly

### **B.3. The Law on Medical Practice**

Within the scope of the field mission it was not possible to examine the content of whatever legislation is in force relating to the medical profession.

*Principles* As with pharmacists (see B.2. above), the law on the medical profession needs to cover a range of topics that include the education, specialization and licensing of professionals as well as the disciplinary measures that exist. However this law, the regulations made under it, must also include certain issues directly relevant to medicines, notably as regards rational prescribing.

*Available material* Legislation and regulation relating to physicians falls outside the present consultancy but should in due course be examined.

*Status* One repeatedly encounters reports of irrational and excessive prescribing.

*Recommendations* Subject to the overriding need to set clear priorities because of limits on available resources the NFMB should be advised to consider whether measures can be envisaged to improve the rationality of prescribing by physicians, e.g. through the dissemination of impartial information and advice to professionals and the public on the appropriate use of medicines.

### **B.4. The Avicenna Institute**

*Principles* The Avicenna Institute was created some sixty years ago before other bodies existed in the drug field and was intended to play a wide role in public health and in the development of medicines. In a modern health setting it can perhaps best be regarded as playing a role that in other countries is accorded to a "Public Health Institute", i.e. a state institution where scientific work is undertaken to complement the services provided by the health care system and the regulatory and administrative arms of the Ministry of Public Health. In Afghanistan it was for many years primarily involved in drug production; in more recent years it has played a role in drug evaluation and approval. As drug policy and law develop, the role of the Institute will probably need to be redefined.

*Available Material* During the 2003 MSH consultancy, a draft document entitled "Principles and Mandates of the Avicenna Pharmaceutical Institute" was drawn up and submitted to the Workshop held in that year; it was revised in the light of the discussions and finalized on 1.09.2003. In it a series of specific tasks were accorded to the Institute (notably operation of the proposed National Medicines Agency, the Medicines Information Centre, the Quality Control Laboratory, the Poisons Information Centre, the promotion of Rational Use and the conduct of medicinal research.

*Status* It is not clear whether any use was made of the 2003 proposal, but the NMFMB Task Force should be alerted to its existence.

*Recommendations* The proposal of 2003 was a useful inventory of possible tasks, some of which have continued to be neglected and it may be helpful to the NFMB in proposing future structures.

### **B.5. Controlled medicines (Dangerous drugs, narcotics)**

*Principles* The global system of for control of dangerous drugs is maintained by the International Narcotics Control Board with its bureau in Vienna and most or all nations are signatories to the relevant Conventions.

*Available Material* The agreed principles of control have been assimilated into Afghan law.

*Status* Despite the existence of a legal regimen it is widely recognized that the flow of opiates and other narcotics is essentially out of control in Afghanistan, with a massive culture, trade and export and virtually free sale in pharmacies of medicines that officially subject to severe restrictions on supply and use.

*Recommendations* The NFMB has not formally been given responsibility for dealing with this field but in view of the serious health implications of illegal trading for the fulfillment of Afghanistan's obligations to the international public health regime it cannot reasonably be ignored when the entire field of medicines is reviewed. It could be helpful to seek the advice of the specialized Unit dealing with this matter inside WHO's Pharmaceutical Program at Geneva to determine what steps might realistically be taken to contain this serious problem.<sup>8</sup>

### **C. REGULATIONS TO BE DRAWN UP UNDER THE LAW**

*Note: The order of presentation is arbitrary and not intended to indicate priorities*

#### **C.1. Regulation on the licensing and classification of medicines**

*Principles* Part III (Article 8) of the draft Law on Medicines of 2003 laid down general procedures and standards on these matters, according primarily responsibility for them to a National Medicines Agency (NMA). It is not yet clear whether the final text of the law as published in 2006 adopted the same approach; a complete translation of the law is still awaited.

*Available material* In line with Article 8 of the draft Law a draft "Regulation on the Licensing and Classification of Medicines and Designated Medical Products" was drawn up and submitted on 25.08.2003.

*Status* It is clear that no National Medicines Agency or a comparable body was ever established, one consequence being the current fragmentation of this work. No use appears to have been made of the draft regulation.

*Recommendations* Since the principles laid down in the draft regulation of 2003 are universally valid, a definitive regulation is now needed and the NFMB may wish to formulate one as its planning develops.

#### **C.2. Advertising and promotion of medicines**

*Principles* The general principle is that when a medicine is approved for sale the body concerned will when registering it approve the information relevant to it (properties, effects, dosage, side effects etc.) and that all advertising and promotion must be in line with this approved information. The draft law laid down the general principle as well as stating that all advertising texts would require advance approval.

*Available material* A three-page draft regulation on advertising and promotion was prepared and submitted to the Workshop during the 2003 consultancy (document dated 29.08.2003).

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*Status* While translation of the definitive Law on Medicines is awaited it is not clear whether it adopted these general principles. Certainly no system to control advertising and promotion currently exists in this field.

*Recommendations* Again subject to the need to work selectively because of limited resources, the NFMB Task Force could consider to what extent indefensible advertising can be countered, e.g. through the introduction by the trade as a whole of a voluntary system of self-monitoring, such as has been employed in various other countries, such as Australia.

### **C.3. Manufacturing, Importation and Wholesaling of Medicines**

*Principles* Although these are three separate matters they can conveniently be combined into a single regulation under the Medicines Law.

*Available material* Two sets of regulations were drafted for the Workshop in 2003 namely, the one on importation and wholesaling and the other on manufacturing. Some of the elements of these drafts prove to have been used in a "Resolution on the Manufacture and Importation of Drugs and Medical Equipment" (20 pages) of which a translation is available. The material is undated but it appears to be recent. The word "Resolution" is used in the title but the document is clearly a regulation and makes reference to the "Drugs Law" as well as to legislation in the field of business. Though the title makes no reference to wholesaling, a section is devoted to this topic.

The document as a whole is comprehensive and seems likely to be compatible with the Law on Medicines, though an exact comparison must await a definitive translation of the latter. Authority in various matters is vested in the GDPA. Provision is made for licensing and inspection, the conditions for operation are reasonably defined, special provision is made for handling narcotics and requirements are set for the employment of pharmacist in the firms concerned. There is reference to the applicability of "international standards" but it is not clear which are meant.

*Status* The regulation appears to be officially in force though, as with the other legal instruments, one must doubt whether it is actually being implemented in practice.

*Recommendation* There seems to be no immediate need to revise this document, but in due course the NFMB will clearly need to determine whether it is actually being enforced. The widespread availability of unregistered medicines clearly suggests that the provisions on importation and wholesaling are not being strictly applied.

## **D. MISCELLANEOUS MATTERS ON WHICH NEW OR REVISED DRAFTS ARE LIKELY TO BE NEEDED AND SHOULD BE IMPLEMENTED**

The implementation of health policy in the drug field requires a wide range of legal instruments, some of them concerned primarily with medicines and others dealing with related fields but concerned to some extent with drug use. The following list covers the most significant topics insofar as these have not been covered earlier in this report. Where information is known to be available on existing rules or drafts this is indicated in notes.

On most or all of these matters the team would on request be able to provide model texts, based on successful examples from other countries but adapted to Afghan needs.

D.01 Vaccines and vaccination procedures  
Legal provisions exist but the situation has not up to this point been examined

D.02 Traditional and complementary medicines

The consultancy in 2003 drafted a regulation on this matter dated 25.08.2003; it does not appear have been adopted or put into effect

D.03 Possession of medicines and duty or competence to hold and issue them

- a. Institutions
  - General and specialized hospitals
  - Nursing homes
  - Ships and aircraft
- b. Health professionals
  - Physicians and medical specialists
  - Dentists
  - Midwives and obstetric nurses

Measures in these fields appear to be lacking, but further information is needed.

D.04 Quality Assurance and Control

Although the lack of coordinated system of quality assurance and control is a prominent finding by the present Mission (and in earlier consultant reports by MSH and others) it is not clear that the issue as a whole is dealt with in any specific legal document. It featured prominently in the draft Policy document of 2003 and when the current versions of the Laws have been translated the question will be whether it is adequately covered in the Law on Medicines and the Law on Pharmacy so as to provide a basis for overall action.

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D.05 Cost control and price control

The high prices of many drugs represent a heavy burden both on the health system and on individuals. Part XII of the Draft Law of 2003 made basic provision for measures in this field and a Policy Outline of 29.08.2003 formulated concrete steps that could be taken but no further progress has been made. It has been pointed out to the present team that according to the Afghan Constitution the prices of goods must be determined by the market, i.e. not by official controls. There are however various other means of controlling costs in this field (limited prescribing lists, competitive tenders to the public sector, use of generics etc.) and these merit consideration; to implement them, specific regulation will be needed.

D.06 Rational Use of Medicines

Part X of the Draft Law of 2003 dealt with this issue but there seems to have been no regulation or implementation

*Status:* there is a chapter on rational use of medicine in "drug law", it covers dispensing of unlicensed medicines, prescribing, dispensing, evaluate prescriptions, education, ADRs, advertising, administration and disposal.

*Recommendation:* Certain articles in this chapter are brief; the title of an article does not correspond with the actual content. This needs to be reviewed to assess its adequacy and comprehensiveness.

D.07 Provisional of impartial information on medicines

- a. To health professionals
- b. To the public

Section V of the Draft Law of 2003 was intended to create a Medicines Information Centre for this purpose.

*Status:* there is an article in Rational use of medicine chapter to cover this, but the implementation of this is unclear.

*Recommendation:* the content is brief and general, this needs to be reviewed to assess it's adequacy and comprehensiveness.

D.08 Adverse reaction monitoring

The majority of countries now have measures to detect serious new adverse effects and drug interactions reported nationally, to take cognizance of similar information from other countries, and to adapt drug licenses and information accordingly. Unless relevant measures have been included in the officially adopted Law on Medicines, formulation and implementation of a relevant policy and procedure needs to be considered by the NFMB.

*Status: there is an article in Rational use of medicine chapter on analyzing and publishing of ADRs, but there is no mentioning of the monitoring of ADRs*

*Recommendation: since the article mentions it is the responsibility of Avicenna on ADRs, but it is unclear whether a draft document entitled "Principles and Mandates of the Avicenna Pharmaceutical Institute" is implemented, therefore it is unclear whether this is being implemented.*

#### D.09 Establishment of a National Poisons Center

Cases of poisoning are not limited to drugs, but the matter can well be dealt with in the framework of drug law. A poisons centre has expert knowledge of poisons of all type and the treatment of poisoning and can provide immediate information countrywide by telephone in emergencies. The Centre can be combined with that handling Drug Information or Adverse Reaction Monitoring (see above).

#### D.10 Destruction of medicines and related goods

Expired or damaged supplies and unwanted donations need to be collected and destroyed in an effective and environmentally acceptable manner. Provision needs to be made for this where medicines are concerned though the actual destruction may be handled in a plant dealing with other materials as well (e.g. industrial chemicals).

#### D.11 Clinical trials in volunteers or patients

It does not seem that there is a significant volume of clinical investigation in Afghanistan and the need for special regulation may well be considered to be a low priority issue. However, many countries have now introduced strict regulatory requirements and the more restrictive these become (and the higher the costs become of performing research in those countries) the greater the temptation for pharmaceutical firms and others to move such studies to countries where requirements are limited or absent; this has happened elsewhere, and it could be a reason to create a procedure for clinical trial certification to protect the population of Afghanistan.

#### D.12 Designation of analogous products

While a medicine is usually readily recognizable as such, a range of other products exist that raise similar public health issues and that may therefore need to be "designated" so that they can be dealt with under drug law. They may include for example certain cosmetics having pharmacologically active components (or for which health claims are made), some surgical materials and a number of medical devices for internal placement (heart valves, copper-based intrauterine devices). The draft Medicines Law of 2003 made provision for designation, but it is not clear that a procedure exists in current law.

#### D.13 Policy on Access to Medicines

The Canadian CBAM Project and other consultancies have clearly profiled the serious problems with access to medicines in Afghanistan but the issue as a whole does not appear to be covered in any official policy document. This would appear to merit the attention of the NMFB when priorities are set.

#### D.14 Coordination with the veterinary drug sector

It seems likely that veterinary medicines will remain primarily an issue for the MAIL. Since however the majority of the medicines used in animals have the same components as the corresponding human drugs some collaboration between the two groups of assessors is vital to avoid duplication and inconsistency.

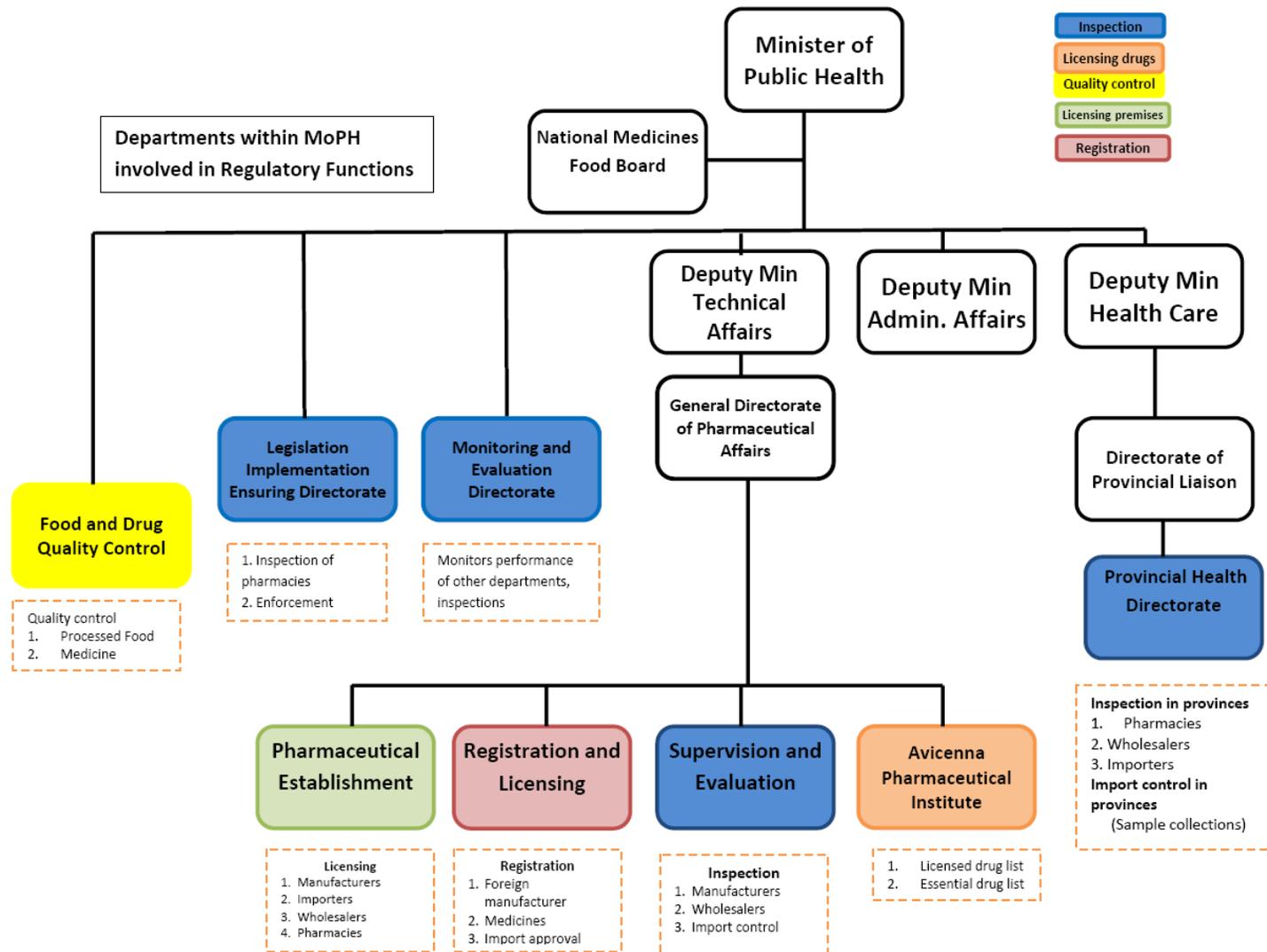
#### D.15 The status of Health Inspectorates

This issue merits careful consideration by the Task Force once a satisfactory series of regimes have been created in and around the areas of medicines, medical practice, pharmacy and manufacturing. As many

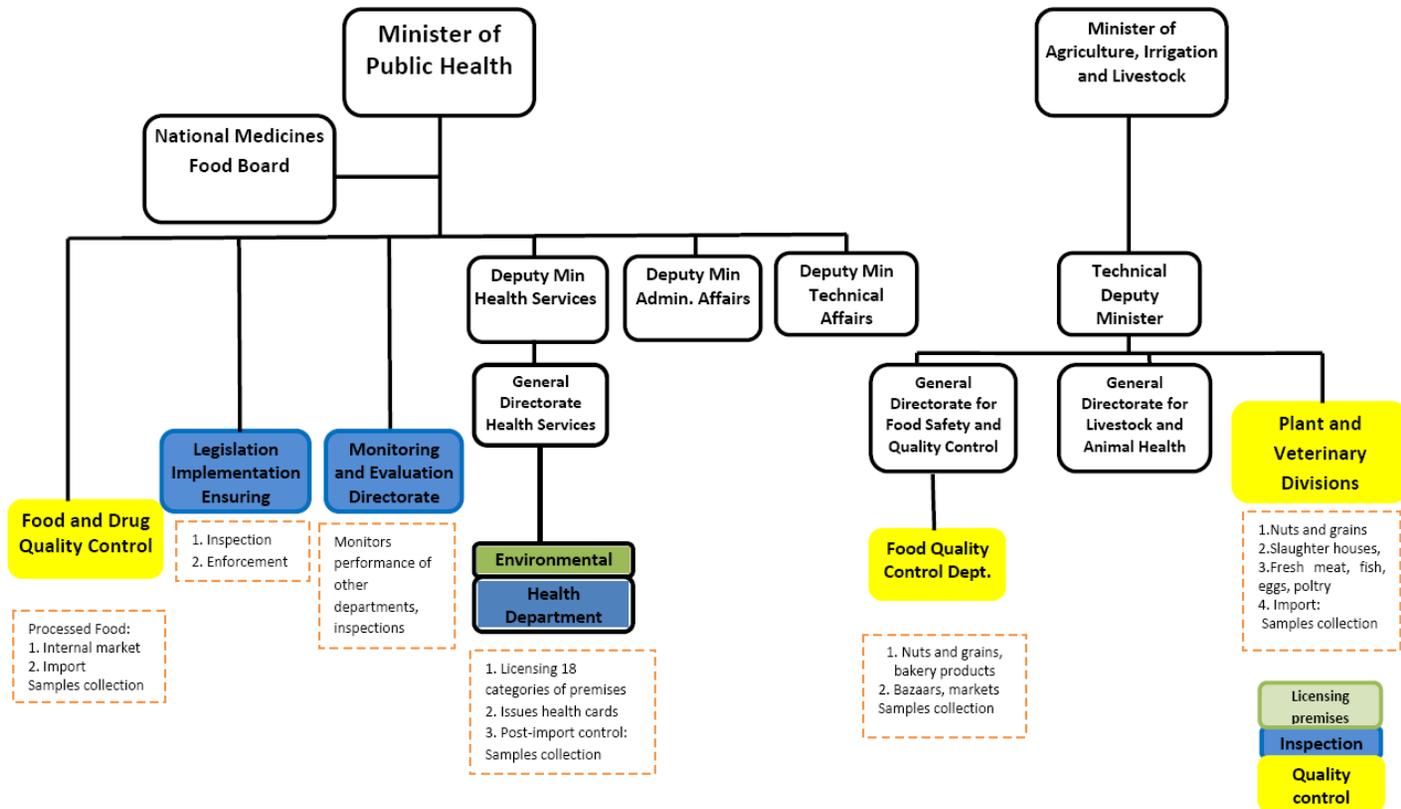
countries have found, the proper functioning of these sectors can only be guaranteed if inspection is authoritative, well-funded, honest and efficient. Corruption is certainly the major risk in the inspection process, but incompetence is another common defect. The best inspectorates in the health field are clearly those that enjoy fully independent status, free of political or financial influence. An inspectorate of this type can very well handle the inspection of various entities (physicians, pharmacists, manufacturers etc.), employing specialists in each of these fields. Funding by way of inspection fees is feasible and advisable.

As in the other areas covered in this section of the report, foreign models can be identified to serve as a basis for planning in Afghanistan.

## APPENDIX II: MINISTRIES AND DEPARTMENTS INVOLVED IN REGULATORY FUNCTIONS FOR MEDICINES



## APPENDIX III: MINISTRIES AND DEPARTMENTS INVOLVED IN REGULATORY FUNCTIONS FOR FOOD



Ministries and Departments involved in Regulatory Functions for Food Products

## APPENDIX IV: OBJECTIVES AND INDICATORS

### Short term:

Objectives	Indicators
1. Define roles, responsibilities of the various stakeholders involved in regulatory functions.	1. Formalization of roles and responsibilities
2. Establish effective communication and coordination channels (internal)	2. Established structural and functional linkages in a system of accountability
3. Record keeping and documentation a. meeting minutes, review reports, application forms, etc.	3. Evidence and traceability - % meetings with minutes, % of application reviewed.
4. Registered and updated database, medicines, licensed premises	4. a) Established database for medicines, licensed premises b) % of medicines found to meet current norms and standards
5. Finish Human resources assessment	5. Drafted human resources assessment report with competency gaps and training needs

### Medium Term:

Objectives	Indicators
1. Establish guidelines, standard operating procedures	1. % of regulatory functions with established guidelines, standard operating procedures
2. Review National Medicine Policy	2. Updated National Medicine Policy
3. Update legislation on medicines	3. Updated legislation on medicines
4. Establish legislation on food products	4. Established legislation on food products (include law, regulation and act)
5. Coordinate food regulation with respect to areas of common concern, e.g. food fortification, vitamin supplements	5. Records of actions taken on matters of common interest
6. Determine operating cost to develop a sustainable revenue system	6. Developed revenue system to cover all operating cost
7. Plan to develop human resources	7. Incorporated human resources strategic plan to national level human resources planning
8. Establish effective communication and coordination channels (external)	8. a) Number of public and professional communications issued b) % of medicines found to meet current norms and standards c) Number of reports on suspected adverse reactions submitted nationally

### Long Term:

Objectives	Indicators
1. Functional regulatory system in place appropriate to a phase of economic recovery	1. a) % of medicine registered b) % licensed premises compliant with current norms and standards c) % of medicines in the market meeting current norms and standards d) Number of reports on suspected adverse reactions submitted nationally

## APPENDIX V: IMMEDIATE FOLLOW-UP ACTIVITIES

### Timeline for Developing ToR For NMFB and Establishment of Secretariat office

Month	Activity	Indicators
March	Process for developing TOR for NMFB & secretariat	Process for developing TOR completed
	Establish the need for the review of the TORs	
April	Present process to NMFB Taskforce	Process for developing TOR agreed with taskforce
	Agreement on the team responsible for the development of the TOR (i.e. Taskforce plus co-opting others if necessary)	
	Present process to NMFB Board	Process for developing TOR approved by Taskforce and Board
	Establish the TOR framework	TOR framework developed
May	Stakeholders Workshop on TOR for NMFB and secretariat	Draft TOR developed
June	Draft TOR based on stakeholders input	Draft TOR developed
	Check draft TOR for consistence with law and functions of other departments involved in regulatory activities	TOR should be consistent with law and applicable requirements
July	Draft circulated for comments	Collation of comments on draft TOR
	Finalize TOR and agreement with stakeholders	TOR finalized and agreed with stakeholders
August	TOR submit for adoption or approval to NMFB board	Revised TOR approved

## APPENDIX VI. MEETING SCHEDULE

No	Date	Activity	Comments
1.	23 <sup>rd</sup> Feb 2011	Meeting with NMFB Taskforce	Review and agree on proposed option based on the assessment report. Agreed to proceed with option of strengthening the NMFB Board to play an oversight and coordination role for regulatory activities
2.	27 <sup>th</sup> Feb 2011	Meeting the Quality Assurance Committee of the GDPA	Clarify some issues related to regulatory functions within GDPA for medicines.
3.	28 <sup>th</sup> Feb 2011	Meeting with staff at FDQCL at MoPH.	Clarify some issues related to Quality Control (QC) – for both food and medicine.
4.	2 <sup>nd</sup> Mar 2011	Meeting with Chair of the NMFB Taskforce at MoPH	Briefing with the Chair on the proposed strategy for implementing the identified option in preparation of the Taskforce meeting on the 3 <sup>rd</sup> of March 2011
5.	3 <sup>rd</sup> Mar 2011	Meeting with NMFB Taskforce	Strategic approach to implement identified option
6.	3 <sup>rd</sup> Mar 2011	Meeting with NMFB	Clarify some issues and their perception of how

		representative from private sector	the system is currently working
7.	4 <sup>th</sup> Mar 2011	Meeting with consultant from Development Alternative Inc (DAI)	Understanding their role in food safety and share any information relevant for regulation of food
8.	5 <sup>th</sup> Mar 2011	Meeting with consultant and staff from Trade and Accession Facilitation for Afghanistan (TAFA)	Understanding their role in food safety and share any information relevant for regulation of food
9.	7 <sup>th</sup> Mar 2011	Meeting with Chair and few members of Taskforce	To review the presentation and briefing for the Minister before the meeting of the full board
10.	9 <sup>th</sup> Mar 2011	Meeting with NMFB full board	Presentation of the taskforce recommendations on option selection and action plan. Board agreed with recommendations and next steps. Taskforce mandate extended to working on next steps to implement the action plan
11.	11 <sup>th</sup> Mar 2011	Briefing with SPS team on next steps	Preparation of milestones for action plan and agreement on next steps