



**ISLAMIC REPUBLIC OF AFGHANISTAN**  
**MINISTRY OF PUBLIC HEALTH**  
**GENERAL DIRECTORATE OF PHARMACEUTICAL AFFAIRS**



**Terms of Reference**  
**National Medicines and Food Board**

**22 October, 2011**

## **Preface**

National Medicine Board was established in 2003 as a regulatory department within the Ministry of Public Health (MoPH) as the highest decision making body in the areas of pharmaceutical affairs and medical equipment as well as the troubleshooting(مشكلات) center for resulting problems and challenges of this field. In response to the growing challenges of medicine and food administration and with the vested (داده شده واگذار شده) power to MoPH, in 2009 the National Medicine Board was expanded to the National Medicines and Food Board (NMFB). The mandate (حکم فرمان) of the NMFB expediting (تسريع سرعت بخشیدن) reforms and coordination of efforts (كوشش تلاش) related to administration and regulation of medicines and medical equipment, food products, cosmetics and sanitation products, traditional medicine and homeopathy, manufacture and import of non-essential and food and medicine items, and quality control of above mentioned items.

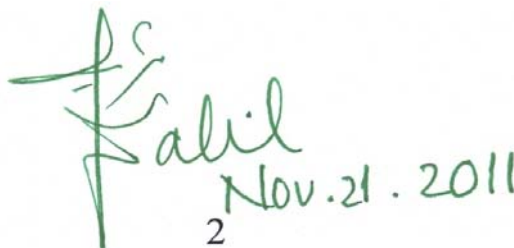
In order for the Board to achieve its established organizational goals, a capable and strong system of medicine and food administration at national level is urgently and insistently needed. Thus, in September/October 2010 the General Directorate of Pharmaceutical Affairs (GDPA) with the financial and technical support of Management Sciences for Health/Strengthening Pharmaceutical Systems (MSH/SPS) reviewed regulatory framework and structure for medicines and food in Afghanistan. As a result of the review, three options for the establishment of such a regulatory Board in the field of medicine and food administration were proposed. The first option of improving capacity of the existing National Board to perform the function of a National Medicines and Food Administration was favored and approved by MoPH. Relevant short, medium and long term action plans were drafted and amendments to the terms of reference (TOR) for the new National Medicines and Food Board were included into the short term reform plans of MoPH. During a two-day workshop held in 2011 participated by 84 representatives of relevant and cooperative authorities a comprehensive TOR for the new Board was proposed and submitted for further debate and discussion by the relevant authorities.

Ultimately, the comprehensive TOR for the Board reflecting the unprecedented efforts and dedication of the Board members, national and international advisors and other stakeholders has been finalized. The MoPH would like to take the opportunity to appreciate the efforts of all who were involved in the process of drafting, reviewing and approval of this utmost governing document, and the technical and financial support of MSH/SPS (Management Science For Health/Strengthening Pharmaceutical System) funded by United States Agency for International Development (USAID). We hope to have their usual support in the further undertakings of MoPH.

The MoPH proclaims this document as the imposed terms of reference for the activities of the National Medicine and Food Board (NFMB) with effect from 22 October, 2011. This document overrides the previous version developed for the same purposes in 2009. The MoPH with a positive note of appreciation for the diligent efforts of international community and private sector in the development of this significant document would like to appreciate their continued assistance in the regulation of medicines and food.

Regards.

Suraya Dalil, MD, MPH  
Acting Minister of Public Health  
And NMFB Chairperson



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## ACRONYMS AND ABBREVIATIONS

API	Avicenna Pharmaceutical Institute
EDL	Essential Drug List
FAO	Food and Agriculture Organization
GDPA	General Directorate of Pharmaceutical Affairs
LDL	Licensed Drug List
MAIL	Ministry of Agriculture, Irrigation and Live Stocks
M&E	Monitoring and Evaluation
MoPH	Ministry of Public Health
MSH	Management Sciences for Health
NMFB	National Medicines and Food Board
SPS	Strengthening Pharmaceutical Systems
TOR	Terms of References
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WFP	United Nations World Food Program
WHO	World Health Organization
HPIC	Health Partners International of Canada

## **Acknowledgment**

The MoPH acknowledges the contribution of all stakeholders listed below who were involved in the development of this TOR, and is also grateful to the Management Sciences for Health (MSH) /Strengthening Pharmaceutical Systems (SPS) Program for the technical support, with the financial assistance of US Agency for International Development (USAID). I am looking forward to seeing more such programs implemented by this particular project.

Our sincere appreciation to the following agencies and their staff for their active participation in the development and finalization of this TOR—

### **NMFB TOR Revision Taskforce Core Team**

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### **International Consultants**

- Dr. David Lee, MSH/SPS
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### **Participant List of NMFB Consultative Workshop (Who provide comments and inputs and review and finalize the NMFB TOR)**

#### **Ministry of Public Health (MoPH)**

- HE Dr. Nadira Hayat Burhani, MoPH Deputy Minister
- Dr. Noor Safi, MoPH Advisor
- Mr. Ziaulhaq Ahmadi, MoPH Legal Advisor
- Dr. Ahmad Jan Naim, Policy and planning general director
- Dr. Abdulrab Wahidi, Central Medical Stock director

- Mr. Hayatullah Nawabi, Procurement manager of General Directorate of Administrative Affairs
- Dr. Bashir Noormal general director of Afghanistan Public Health Institute
- Dr. Habibullah Ahmadzai, Director of International relation
- Dr. Abraham Kamil, Director of Legislation Implementation Ensuring Directorate (LIED)
- Dr. Abdul Manan Saidi, Inspection manager of public and Private of LIED
- Dr. Amir M. Farahi, inspection manager of pharmaceutical establishment of LIED
- Dr. Khisraw Yousufzai, Monitoring manager of MoPH/ M&E Directorate
- Dr. Abdul Maruf Jalily, Evaluation manager of MoPH/M&E Directorate
- Dr. Sadia Faiq Ayoubi, Director of Reproductive Health
- Dr. Kazim Naimi, Director of Pharmaceutical enterprise
- Dr. Hakim Aziz, Director of provincial health directorate
- Dr. Ajmal Yadgari, CPDS coordinator
- Gual Gut dost, Manager of EPI
- Dr. Sultan M. Dawran, Licensing manager of Environmental health directorate
- Mr. Mire Ghafoor, Inspection Manager of Environmental health
- Dr. Yaqoub Azimi, HIMS manager
- Pharm. Amina Rustaqi, Medicine Quality Control (QC) Laboratory manager
- Pharm. Basir Ahmad, Food QC Lab manager
- Dr. Zarmina Safi, Manager of Nutrition dept
- Dr. Khalid Siddiq, National Tuberculoses program
- Dr. Rouhullah Satary, Wazir Akbar khan Hospital
- Pharm. Nazir Ahmadzad, GDPA/API
- Pharm. Abdul Hafiz Qurishi, Registration and Licensing Manager, GDPA
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- Pharm. Khalil Khakzad, Pharmaceutical Planning Manager, GDPA
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- Pharm. Nazir Haiderzad, Pharmaceutical Planning Department, GDPA
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- Dr. Noor Rahman, Manager of Quarantine Department
- Dr. M. Aziz Osmanzai, QC Manager of MAIL

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- Dr. Pohanwal Mohammad Nassim Sediqi, Dean, Professor of Pharmacognosy
- Dr. Aqa Mohammad Jakfar, Associate Professor, Head of the Pharmaceutics Department

**University of Kabul Faculty of Agriculture**

- Professor Mohammad Yasin Mohsini, Dean

**Kabul Medical University**

- Dr. Rafi Rahmani, Pharmacology Department Lecturer

**Gazanfar Institute of Health Sciences (GIHS)**

- Dr. Saniullah Zalmay, Deputy Director
- Dr. Marim Fahim, Lecturer of Pharmaceutics

**Afghanistan National Standards Authority**

- Dr. M. Wakil Rahimi, Food products manager
- Pharm. Hamid Formoly, Medicines and Cosmetics Depat. Manager

**Expanded Programme on Immunization (EPI)**

- Mr. Gual Gut Dost, National EPI Manager

**Ministry of Defense (MoD)**

- Dr. Shersha Ahmadi

**Ministry of Commerce and Industry (MoCI)**

- Mr. Mahbobullah Wazirwal, Member of legal and regulation directorate

**National Security**

- Mr. Saleem Khan, Medicine Procurement Officer

**Ministry of Justice**

- Ms. Nazifa Hashimi, Member of Educational, Cultural and Health Legislation Department

**Donor Agencies**

- Tech-Serve/USAID representative
- Dr. Sefatullah, EU representative
- Dr. Hangama Hamid, WB representative

**International Organizations**

- Dr. Tahir Ghaznavi, UNFPA representative
- Mr. Rahimullah Rahimi, UNICEF representative
- Dr. Ahmadshah Pardis, Essential medicines officer. WHO
- Mr. M. Akbar Shahrestani, Nutrition Dept. FAO
- Dr. Alim Attarud, HPIC Manager
- Pharm. Abdullah Masood, DMU program manager, MSH/Tech-serve
- Pharm. Ahmad Jawid Ehsan, Quality Assurance Officer, MSH/SPS
- Pharm. Noor Ahmad Zulal, Quality Assurance Officer, MSH/SPS
- Dr. Mir Mohammad Omar Atefi, National Medicines and Food Consultant, MSH/SPS
- Pharm. Farid Ahmad Sarwary, Functional Analysis Consultant, MSH/SPS
- Pharm. Qudratullah Taban, Pharmaceutical HR Assessment Consultant, MSH/SPS

**National and International NGOs**

- Dr. Majid Siddiqui, HN-TPO Country Director
- Dr. Yasin Rahimyar, CAF Director
- Dr. Asadullah Noori, Medicines National Officer, AKHS

**Private Sector**

- Mr. M. Ismail Daqiq, Representative of Medicines sellers Associations
- Eng. Said Noor shah Rohani, Representative of Manufacturers Associations
- Mr. Mohsin Sahil Parwani, Medicines and medical equipment importer association
- Dr. Faiaze Safi, Deputy of Physicians association
- Pharm. Junaid Namati, Member of Pharmacist association
- Mr. Qary Shafiullah, Traditional medicine association



## **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. The regulation of medicines is enshrined in the Medicine Law which was established in 2003 and its accompanying regulations. The National Medicine Board (NMB) was established in 2003, as an advisory BBoard to the MoPH. According to the Medicine Law (2008), it is the highest decision making entity on the issues related to pharmaceuticals. In 2009, the Board was expanded by MoPH into National Medicines and Food Board (NMFB) to oversee and take decisions on issues related to medical devices, food stuff, cosmetics, sanitation equipment, pharmaceuticals and traditional medicines. The current NMFB is composed of the following stakeholders: directorates of Ministry of Public Health, other line ministries, private sector, National Office of Norms and Standards and United Nations Agencies.

## **Purpose of the Board**

The aim for the establishment of the NMFB Board 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.

## **Scope of Work**

Provide coordination, oversight and advisory services in relation to the regulation of medicines and food products. The Board 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.

Specifically 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.

### **Structure of the Board**

1. For the efficient exercise of its functions, the Board shall establish a General Medicines Committee and General Food Committee.
2. Any action or decisions taken by the Committees shall be reviewed by the Board.
3. The Board may establish any Committees (*for example Quality Assurance Committee*) or sub-Committees in which may be vested and on which may be imposed such functions of the Board as the Board determines.
4. Any General Committee or Sub-Committee established by the Board shall include at least one person who is a member of the Board and shall be chaired by a member of the Board.
5. The Board may appoint persons who are not members of the Board to the Committees or sub-Committees.
6. Each General Committee shall consist of a minimum of 5 and maximum of 10 members.
7. Each Sub-Committee shall consist of a minimum 3 and maximum of 6 members.
8. Members from Government agencies who are appointed to the Board shall be permanent members or employees of such agencies.

### **Composition of the Board and Committees**

1. The Board shall consist of not less than 15 and not more 20 members as may from time to time be determined and appointed, in terms of Chapter Two, Article 3 of the Medicine Law, by the Minister of Public Health.
2. Members of the Board shall include –
  - A. Core Expertise (Board members):
    - Policy and Law (Medicines and Food)
      - Minister of Public Health as the Chairperson;
      - General Director of Pharmaceutical Affairs as the Deputy Chairperson;
      - Head of Avicenna Pharmacy Institute (API) as a Member;
      - Director of Environmental Health as a Member;
    - Legislation and Regulation (Medicines and Food)
      - Director of Legislation Implementation Ensuring Directorate as a Member;
      - Director of Monitoring and Evaluation of MoPH as a Member

- One Representative (Related professional body) from the Department of Coordination of Private Sector of the Ministry of Public Health, as a Member
- Academic (Medicines and Food)
  - Two professors from relevant department of pharmacy by Selection of Faculty of Pharmacy as Members;
  - One professor of the Pharmacology Department of Kabul Medical University by selection of the university as a member;
- Manufacturing (Medicines and Food)
  - One representative (professional and or expert of Pharmaceutical) from Pharmaceutical Products Producers as a member;
  - One representative (professional and or expert of Food) from Food Products Producers as a member;
- Quality Assurance (Medicines and Food)
  - Manager of Medicines and Food Quality Control as a member;
  - One representative from Afghan national Standardization Agency (ANSA) as a member;
- Trading and Distribution (Medicines and Food)
  - Director of Pharmaceutical Enterprise as a member;
  - One representative (professional and expert of pharmacy), from national association of medicines manufacturers as a member;
  - One representative (Professional and or expert of pharmacy) from National Association of Medicines and Medical Equipment Importers as a member;
- Clinical And Dispensing (Medicines)
  - One internal medicine specialist who work in hospital appointed by selection of the MoPH minister as a member
  - One surgical specialist who work in hospital appointed by selection of the MoPH minister as a member;
  - One pharmacist with clinical pharmacy background or experiences by selection of the MoPH minister as a member;
- a. Observers
  - Observes of the board shall provide technical and financial supports to the board.
  - One representative each from WHO, FAO, WFP, SPS, HPIC and UNICEF as observers (not voting members)
- B. Members of General Committees / Sub-Committees of the Board:

The Committees of the Board will be established by the Board, based on the involvement and expertise of individuals in medicines and food related affairs by selection of members will be made from below agencies, stakeholders and organizations:

  - One representative from Narcotics Drugs Regulation Committee as a Member;
  - One representative (professional and or expert of Food) from food products importers as a member;
  - Two representatives from MAIL (one veterinary medicines expert and one food expert)
  - One professional and or expert of food

- One representative (professional and or expert of pharmacy) from National Association of Pharmacists
  - One representative (professional and expert of pharmacy), from the Health Department of the Ministry of Defense as a member;
  - One representative (professional and expert of pharmacy), from the Health Department of Police Forces
  - One representative (professional and expert of pharmacy), from the Health Department of National Security
  - One representative from Kabul Municipality
  - One representative from the Ministry of Finance (Customs)
  - One representative from the Ministry of Commerce and Industries
  - One representative (Professional of Traditional Medicines) from Traditional Medicine Union;
  - One representative of National Environmental Protection Agency (NEPA)
  - One representative from Central Medical Stock of MoPH;
  - One representative from Afghanistan National Public Health Association (ANPHA)
  - One representative (professional and or expert of pharmacy) from Medicine Services Union of Afghanistan,
  - One representative (Veterinary Medicines Department) from Faculty of Veterinary, Kabul University
  - One representative (from food department) from Faculty of Agriculture, Kabul University
  - One representative (professional and or expert of pharmacy) from Kandahar trade and medicine union;
  - One representative (professional and expert of pharmacy), from medicines sellers association;
4. Members appointed to the Board or Committees shall have:
- Appropriate and relevant qualifications and expertise
  - At least five years of professional experience or familiarization with the relevant laws and policies
  - Official approval from their departments, agencies and organizations
  - A law abiding attitude and commitment

### **Conditions of Office**

1. A Board member shall hold office for such period is up to five years, as the Minister may fix on his appointment.
2. A member shall be eligible for reappointment by the relevant authority Board.
3. A member shall be expelled from Board upon three consecutive absences from Board meetings without prior notification and non-compliance with accepted standards of the Board
4. A member of the Board shall who is convicted of any crime shall cease to be a member
5. A member shall be a citizen of Afghanistan permanently resident in Afghanistan

## **GOVERNANCE AND MANAGEMENT –**

### **Role and Responsibilities of Board and Committee Members**

#### **1. The Chairpersons of the Board and Committees**

- Hold and control meetings and endorse decisions
- Permanent presence in meetings and decision making (to the extent possible)
- Secure funds (incentives and expenditures)
- Pave the grounds for developing the technical capacity of Board members
- Expedite and follow up the implementation of decisions made by the Board

#### **2. The Vice-chairperson of the Board and Committee**

Discharge the duties of the chairperson in his/her absence.

#### **3. The Secretary of the Board**

- Coordinate with the Secretariat on administrative, financial and technical functions and notify the members of the Board or Committees about meetings.
- Ensure that minutes of meetings and agenda are prepared and circulated in advance to members of the Board
- Organize and facilitate (time, location and transportation) the Board meetings
- Take care of accounts and financial issues of the Board
- Summarize the activities of Committees
- Record and file documents
- Follow up to meetings

#### **4. Members of the Board and Committees**

- Timely and actively participate in the meetings
- Attend meetings regularly
- Make decisions to address medicines and food related issues
- Collect the necessary information on various technical issues to be discussed by the Board
- Contribute actively in developing the necessary documents for the improvement of medicines and food related issues
- Participate in monitoring activities specified by the Board

### **Operating Principles**

1. A member of the Board or Committee of the Board shall consider the national interests of the country above his/her personal activities.
2. The Board shall be impartial and make fair and independent judgment, timely and determined decisions, and remains accessible to all stakeholders.
3. A member of the Board or Committees of the Board shall be committed, honest, and professional in their conduct of activities.
4. Members of the Board shall be specialized, efficient, conscientious and free of any kinds of discriminations based on language, tribe, region, etc.

## **Meetings and Procedures of the Board and Committees**

1. The Board shall convene for the dispatch of business and adjourn, close and otherwise regulate its meetings and procedures as it deems fit.
2. The meetings of the Board shall be held not less than once every month.
3. The Board meetings shall be held on a date agreed upon by all members of the Board or set by the Chairperson of the Board or Committee.
4. The Chairperson of the Board or of a Committee may, at any time and at any place, call a meeting of that Committee.
5. All meetings and decisions of the Board shall be written down in minutes, which shall be filed and kept with the Secretariat.
6. Minutes of the Board meetings shall be taken by the Secretariat and reviewed by the Secretary of the Board before circulation to members.
7. The Board's decisions shall be communicated in writing to the relevant bodies or individuals.
8. The Board shall use both electronic and print media to communicate with the public as the Board may determine.
9. Telephone numbers and e-mail addresses of the Board members shall be kept at the Board Secretariat.
10. Minutes of previous meeting and the agenda for the next meeting shall be distributed to members at least three days before the date of the proposed meeting.
11. Notices on emergency meetings shall be sent to the Board members at least twenty-four hours before the meeting.
12. Two-thirds of the members shall form a quorum for Board or Committee meetings.
13. Meetings of the Board or Committees are considered valid when two-thirds of the members are present.
14. All acts or matters authorized or required to be done by the Board or Committees shall be decided by a simple majority vote at a meeting of the Board or Committee at which a quorum is present.
15. At all meetings of the Board each voting member present shall have one vote on a question before the Board and, in the event of an equality of votes, the Chairperson shall have, in addition to a deliberative vote, a casting vote.

## **Reporting**

1. The Board shall prepare quarterly/annual reports which shall be submitted to the Minister of Public Health and Ministry of Agriculture and Live Stock and Irrigation..
2. Committee of the Board shall present quarterly reports to the Board.
3. The Board's quarterly reports and annual reports shall be made available and accessible to stakeholders

## **Disclosure of Interest / Conflict of Interest**

1. Before accepting any appointment to be a member of the Board or Committee, a member shall disclose any potential conflicts of interest.
2. Potential or actual conflicts of interest by members of the Board shall be identified and declared or disclosed to the Board or the Committee as the case may be.

3. A member with conflict of interest or potential conflict of interest shall take no part in the consideration or discussion of or vote on any issue before the Board or the Committee as the case may be, for any issue in which he/she or spouse of such a member has substantial interest in the matter.
4. If not declared, any person who is aware of the issue shall inform the Board or the Committee.
5. Cases where it is not clear whether or not a conflict of interest is present, shall be brought before the Board and the Board shall make a final decision.

### **Confidentiality Agreement**

1. All members of the Board or Committees shall sign a confidentiality agreement at the time of appointment to the Board or Committee.
2. Decisions and resolutions of the Board or Committee shall remain confidential and no member other than officially designated person(s) shall disclose to any other person the decisions of the Board or Committee.
3. Violators are subject to penalty based on the ... (members' decision or any disciplinary guidelines). Shall the Board members decide, termination of the violator's membership would apply.

### **Performance Evaluation**

1. The Board or Committee shall monitor and evaluate its own performance using laid down standard norms and procedures on a regular basis (quarterly / annually).
2. An independent Committee may be established for the conduct of such performance evaluations.
3. The performance of each member of the Board or Committee shall be evaluated by the Chairperson of the Board,
4. Internal appraisal shall be annually done by the monitoring agency, and external appraisal shall be done by relevant authorities on an annual basis.

### **Remuneration of Members of the Board and Committee**

A member of the Board or Committee shall be paid such allowances / incentives as the Minister, in consultation with the Board, may determine. The payment of allowances shall be subject to availability of funds for such purposes.

### **Funds, Accounts and Audit**

1. The Board shall maintain its accounts based on the financial and budgetary standards of the MoPH.
2. The accounts of the Board, shall be audited in accordance with the standards and procedures of the MoPH,
3. The Board shall establish an Internal Audit Committee and the audit shall take place with the assistance of a national and international auditor.

4. The reporting and responding method has been set for each budget, it shall be audited by financial and relevant Committees and shall report to the relevant authorities.
5. The funds of the Board shall consist of funds from government budgetary allocations, and lawful donations from national and international organizations.
6. The Board shall accept donations with the approval of the Minister of MoPH in consultation with Minister of Finance..

### **Validity of Decisions and Acts of the Board and Committees**

1. Decisions of the Board or Committees shall be in according with official bills, regulation and relevant legislations.
2. Decision made shall not be including the voting of members with substantial conflict of interest on the matter.
3. Decisions of the Board or Committees shall not be in conflict with the national interest

### **Deliverables or output**

1. A coordinated system for regulation of medicines and food products
2. Existence of effective documents, laws, regulations and policies with regard to the production, importation, storage, selling, and distribution of quality medicines and food products
3. Existence of functional systems for preventing the importation, production and use of low quality and unhealthy medicines and food products (protect people's health)
4. Existence of a sound and authoritative institution for improving medicines and food related affairs