



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

Annual Report for the National Medicines & Food Board Annual Activity Report



April 2012 to April 2013

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Foreword

The Ministry of Public Health (MoPH) of Afghanistan is committed to ensuring that all food, medicine and related substances in the country, either produced locally or imported from other countries, are safe, effective and of good quality thereby ensuring protection and sustainable promotion of public health.

To achieve this goal, the MoPH expanded the Medicine Board into National Medicine and Food Board (NMFB) in 2009. As of 2012, the Board established two general technical committee for medicine and for food. The NMFB Board is to advise, coordinate, oversee and accelerate medicines and food-related activities 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.

During the past year the NMFB had notable achievements, which include finalizing the draft food law, start the process to review and update the Medicine Law, establishment of the NMFB Secretariat Office with three staff members and making decisions on number of issues/ problems related to pharmaceuticals and food. The NMFB is playing an important role in development of legal framework for the strengthening of regulation for food and medicines through the coordination and review of the food and medicine laws. It is hoped that the NMFB will continue to expand their activities to address other key challenging issues facing the pharmaceutical and food sector in Afghanistan.

The MoPH acknowledge the contribution of all stakeholders involved in the NMFB activities, the members of the Board, Committees and technical working groups. Furthermore, the Ministry and the people of Afghanistan are grateful to the U.S. Agency for International Aid (USAID) through Strengthening Pharmaceutical System (SPS) project for providing financial and technical support to the NMFB. I am looking forward to seeing more partners and stakeholders taking active participation in the pharmaceutical and food sector.



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

1. Terms of reference

1.1. Brief historical background

The National Medicine Board was established in 2003 and then it was promoted to the National Medicines & Food Board (NMFB) in 2009. According to the Medicine Law (2008), the Board is the highest decision making entity on issues related to pharmaceuticals. Upon its expansion in 2009, the Board's mandate was extended to include foodstuff. According to the current Terms of Reference of the Board as approved by HE Dr. Suraya Dalil, Minister of Public Health in November 21, 2011, the Board's mandate is to advise, coordinate, oversee and accelerate medicines and food-related activities, 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.

1.2. The functions of the NMFB are:

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. Include or exclude drugs from the Essential Drug List (EDL) and Licensed Drug List (LDL) based drug selection standards.
3. Review the total Licensed Drug List and Essential 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. Determine strategic directions 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 affairs.
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 and approve the Afghanistan National Formulary regularly
15. Establish committees for review and updating of EDL, LDL and National Formulary and others scientific and professional committees for relevant affairs.
16. Approve scientific and research programs related to pharmaceutical products and food
17. Review and approve the country's annual need for medicines
18. Supervise all pharmaceutical and food services provision systems in the country



Picture1 Law revision first consultative workshop

1.3. Appointments & Membership of the Board

The appointments of members of the Board are based on the Terms of Reference (TOR) of the NMFB. The current NMFB is composed of the stakeholders consisting of directorates of Ministry of Public Health, other line ministries, private sector, National Office of Norms and Standards and United Nations Agencies.

The Minister of Public Health as the Head of the NMFB delegated Dr. Abdullah Fahim (Technical Advisor to the Minister of Public Health) as the NMFB chairperson from 27/Aug/2012 by letters No 2320. A list of the current membership & affiliations of the Board is attached as appendix (I)



Picture 2 : NMFB meeting chaired by HE Dr. Suraya Dalil the MoPH Minister and Chairperson of the NMFB



Picture 3 :NMFB meeting chaired by Dr. Abdullah Fahim Chairperson of the NMFB

1.4. Committees

The Board fulfills its mandate by working through various Committees & Taskforces were necessary. To this end, the Board has established two Committees, Medicines & Food Committee.



Picture : 4 FC meeting of NMFB



Picture5 : MC meeting of NMFB

1.4.1. Medicines Committee

The Medicines Committee (MC) of the NMFB was established on April 2012 and its TOR and membership approved by the Board and the Minister of Public Health. The current chair of the Committee is Pharmacist. Abdul Hafiz Quraishi Director of General Directorate of Pharmaceutical Affairs (GDPA)

The purpose for establishing the MC is to carry out in-depth technical analysis of all medicines-related issues at the national level, and make specific recommendations to the NMFB. A list of the

current membership & affiliations of the MC is attached as **appendix (II)** and work plan in **appendix (IV)**

1.4.2. Food Committee

The Food Committee (FC) of the NMFB was established on 22 October 2011 and its TOR and membership approved by the Board and the Minister of Public Health. The current chair of the Committee is Dr. Amanuallah Hussaini the Director of Environmental Health of MoPH.

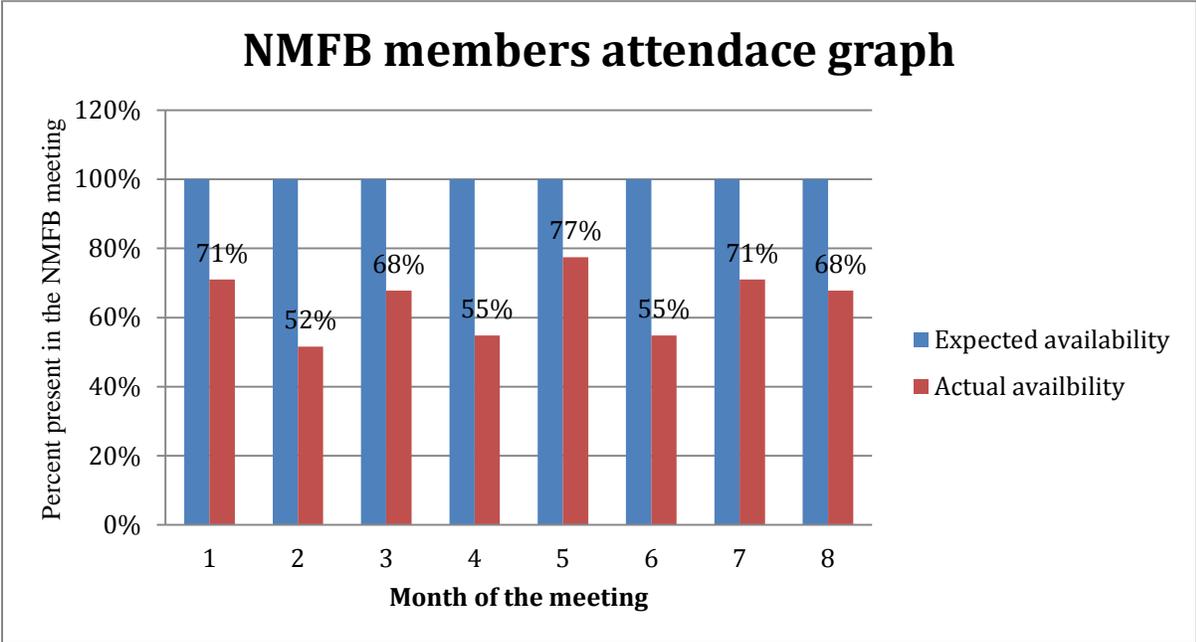
The purpose for establishing the FC is to carry out in-depth technical analysis of all food-related issues at the national level, and make specific recommendations to the NMFB. A list of the current membership & affiliations of the FC is attached as **appendix (III)** and work plan in **appendix (V)**

2. Meetings

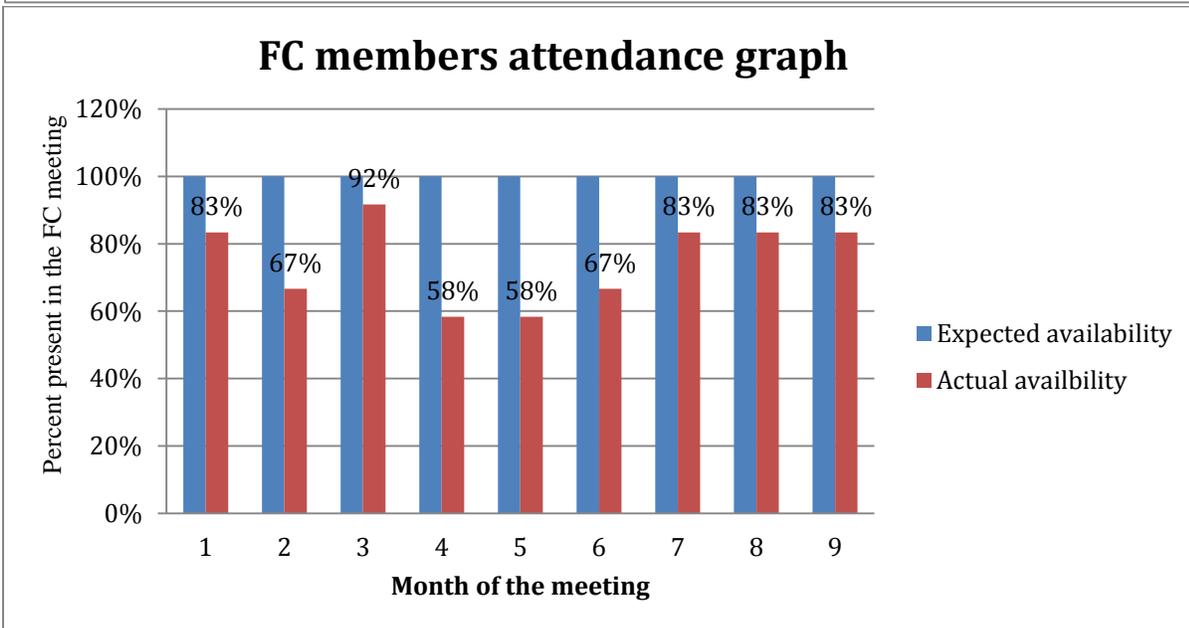
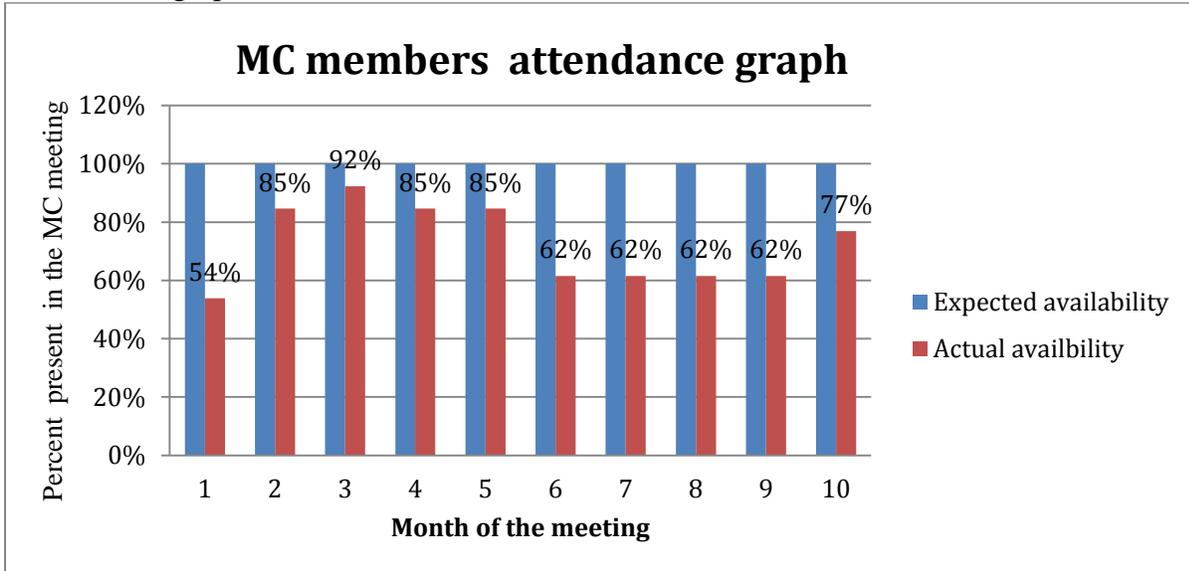
The Board and the Committees meet at regular intervals throughout the year. Below is a table with the summary of the number of meetings held in 2012 – 2013;

No	Institution	Frequency	# Of meetings	Place of meeting
1	Board	Monthly	8	MoPH Library hall
2	FC	Monthly	9	Environmental Health Directorate and MoPH Library Hall
3	MC	Monthly	10	General Directorate of Pharmaceuticals Affairs

During the last year in the NMFB meeting on average **65 %** of the members were present in the meetings. The percentage details of all the meetings are presented in the following graph:



On average in the MC meetings **72%** members were present while in the FC meeting **75%** members were present. The detailed percentage of attendance in the meetings of FC and MC presented in the graphs below:



3. Secretariat

The Secretariat of the NMFb is based at the Ministry of Public Health and consists of three staff members: Medicines Affairs Technical Advisor, Food Affairs Technical Advisor and an Administrative Officer. The Secretariat acts as the interface between the stakeholders, and clients and the NMFb. It is responsible for processing and preparing meetings and minutes for the Board and its Committees, facilitating the communication, implementation and reporting of the NMFb decisions.

4. Summary of the work 2012 – 2013

As the highest decision making body for pharmaceuticals and food, the NMFB's work is currently being aligned according to the revised TOR so that the body focuses on policy issues, coordination of the sector, and resolving problems in the pharmaceutical and food sector.

Operations: The NMFB established two Committees (FC and MC) and approved the TOR & annual work plans for the two Committees. The NMFB also established a taskforce to review the TOR for the establishment of a Quality Assurance (sub) Committee for pharmaceutical sector. This work is still ongoing and will be finalized during the 2013. During previous year the NMFB established the Law review Technical Working Group for the revision of the Medicine law.

The Secretariat for the Board was established and this included recruitment of staff and establishing NMFB's Office at the MoPH. The establishment of the Secretariat with support from the USAID Strengthening Pharmaceutical Systems (SPS) project improved the operations and functions of the Board and the ability to follow up on NMFB's decisions. It is also envisaged that the establishment of the Secretariat will enable the NMFB to coordinate the pharmaceutical and food sectors. There is ongoing work to standardize the processes and procedures of the Secretariat through development of appropriate standard operating procedures.

Develop and review the bills and regulations: The lack of a legal framework for food and the inadequate legal framework for medicines is one of the major challenges affecting the regulation of both medicines and food. To this end, one of the notable achievements of the NMFB is review and approval of the draft food law, which has since been submitted to the Ministry of Justice. Furthermore, the review of Medicines Law was also initiated and the task was assigned to a Technical Working Group (TWG) under the Medicines Committee. Updating and finalization of these two pieces of legislations is one of the important elements in strengthening the country's regulatory system for medicines and food.

Some of the problems in the pharmaceutical sector include, sampling, waste management, illegal importation of raw materials, cosmetics and hygiene products. To address some of these challenges, the NMFB is working on several bills for sampling of food and medicines, cosmetic and hygiene products, pharmaceutical waste management, and importation of raw medicinal materials.

Solving Pharmaceutical and food related problems: Several issues/problems were brought to the NMFB for decision-making. Some of the issues discussed and resolved include establishment of new pharmacies, transferring pharmacies from one place to another, blacklisting of 10 Pakistan Pharmaceutical Companies based on recommendation from the GDPA, restriction of protein products for sale only in pharmacies based on prescription from physicians, among other issues.

Establishing standard systems for medicines and food: The current fees charged for testing are outdated and not adequate to cover some of the costs for conducting the tests. As such, based on request from the National Quality Control Laboratory, the NMFB is currently reviewing the fees for quality control tests for medicines and food substances. Furthermore, the FC is current working on preparing standards for food and related issues.

5. Challenges

Despite the notable achievements in this year, the NMFB faced several challenges, which affected its operation. The members are coming from very diverse backgrounds, and in most cases some have limited experience on the specific issues brought for discussion, thereby affecting the deliberations on the technical issues during the meetings. The NMFB does not have sustainable financial support from the government and depend on financial support from USAID SPS project. Although the members are appointed based on official invitations from the board, some of the members are prevented from participating in some meetings by their departments or institutions. Challenges exist with respect to cooperation and coordination of the various stakeholders involved in medicine and food related affairs. There is lack of cooperation and coordination between different departments and ministries involved in food safety control. Currently, the different departments and ministries are developing multiple legal documents without consultation and cooperation among themselves. There is need for coordination on the development of legal documents (regulations, and bills) with clear separation of roles of different stakeholders i.e. ministry of public health, ministry of agriculture, irrigation and livestock, and local municipality.

6. Future developments

In the coming year, the NMFB will focus on finalizing and having the food and medicine law approved by the government. This will create the appropriate legal basis for some of the changes required in the regulatory system. Given the diverse backgrounds and specialized nature of regulation of medicines and food, the NMFB will focus on capacity building of the members to ensure meaningful deliberations and contributions by members. An important aspect to be considered is sustainability of the system in the medium to long term. Currently the NMFB is entirely supported by the SPS project. In the future, the NMFB will explore other funding mechanisms and partners to support the NMFB and some of the activities, which are currently not funded. The NMFB will continue to work on development of necessary regulations and bills for the proper regulation of medicines and food and this will include regulations for food import, food hygiene, food control and inspection, review the retail pharmacy regulations. To improve the coordination of the sectors, the NMFB will establish periodic reporting and update meetings among the stakeholders and improve communication channels.

7. Good Governance

Confidentiality agreements

All members of the Board and Committees have signed a confidentiality agreement at the time of appointment to the Board and Committees. All the signed agreements are filed with the Secretariat. This system is aimed to maintain confidentiality of issues and discussions brought before the NMFB.

Conflict of interest

All members upon appointment sign a conflict of interest statement. There is no any existing or potential conflict of interest of current members. If there is any issue that can be disclosed during or before the NMFB meeting. At each meeting, members are requested to declare any conflict of interest on the issues on the agenda.

Accountability & Transparency

This is the first annual report for the NMFB and will be available to the public. The Board's semi-annual and annual reports shall be made available and accessible to stakeholders i.e. made available on the MoPH website. Furthermore, the NMFB shall conduct periodic or annual stakeholders meeting to give feedback to and receive comments from stakeholders on the NMFB's work.

8. Appendices

Annex I: Membership of the Board

S/No	Name	Designation	Organization	Telephone	E-mail Address
NMFB Permanent Members					
1	Dr. Abdullah "Fahim"	MoPH Consultant/Head of NMFB	MoPH	0700-276-340	fahim_908@hotmail.com
2	Ph. Ab.Hafiz "Quraishi"	GDPA Director	GDPA	0786-301-030	quraishi_hafiz@yahoo.com
3	Dr. Moh. Kazim "Naimi"	Pharmacy enterprise Director	MoPH	0799-334-765	pharmacy_en@yahoo.com
4	Dr. Ab.Khalil Khakzad	API Director	GDPA	0799-334-765	khalil-khakzad@yahoo.com
5	Dr.Amanullah Hussaini	Environmental Health Director	MoPH	0700-294-312	mnlhh-hussaini@yahoo.com
6	Dr.Sayed Shafi Sadat	Helth Coodinator	OPSC/MoPH	0700-036-371	smssaadat@yahoo.com
7	M.Shafiq Mashal	Farmacy Faculty Lectures	Kabul Univercity	0702-216-900	MSMashal@yahoo.com
8	Bashir Ahmad Bashir	Farmacy Faculty Lectures	Kabul Univercity	0799-264-905	bbbasherahmad@gmail.com
9	Dr.M.Rafi Rhmani	KMU lecturer	K.M.U	0799-303-008	rafi-rahmani2003@yahoo.com
10	Dr.Gh. Darwish	Spidev.Drugs	A.N.S.A	0798-812-905	dr.gdm@hotmail.com
11	Dr.Ab.Wali haiati	Internal Specialist Doctor	Jamhoriat hospital	0700-289-739	wali-hayati@yahoo.com
12	Dr.Khalil Amiri	Surgeon Specialist Doctor	Wazir M.Akaberkhan Hospital	0772-278-095	dr-amirisur@yahoo.com
13	Dr.Sayed Hoamyoon Hassan	Represent of medicines Productions	ANMSO	0700-279-119	kip-director@yahoo.com
14	Al.Haj.Rahimudin Haji Agha	Director of Private Traders Board	MoCI	0700-367-918	raheem-Khqiry@yahoo.com
15	Sayed Asadullah	General Manager	LIED	0799-211-448	
16	Ph.Kamela Sultani	Director of FDQCL	MoPH	0799-331-151	ksultani@gmail.com
17	Dr.Sher M.Faiz	M&E officer	MoPH	0772-014-407	drsher-faiziool@yahoo.com

18	Dr.Aminullah shoaib	EMP	MCN	0775-080-983	dramish@yahoo.com
19	Mohd. Omer Mansoory	Registration Manager	GDPA	0700-289-414	omer_mansoory@gmail.com
20	Haji Mohd.Hassan	Chair of export association	ACCI	0780-016-840	Haji-Hassan-KFNC@yahoo.com
21	Ph.Khan Agha karim Ghazi	General manager of establishment retail pharmacies	GDPA	0700-294-873	-
<u>NMFB oversight members</u>					
1	Ph.M.Zafar Omary	SPS COP	SPS	0700-169-632	momary.@mash.org
2	Ghulabuddin Rashid	SnR Prg. Assistant	WFP	0795-662-003	Gulabuddin.Rashid@wfp.org
3	Dr.Safiullah Nadeeb	Coordinator	WHO	0777-327-530	nadeeb@org.emro.who.ind
4	Ph.Hashmatullah Sadat	Pharmaceutical technical Manager	HPIC	0779-535-602	hsadat@hpicafghnistan.ca
5	Dr.M.Akbar Shahristani	Coordinator	FAO/MAIL	0799-375-187	mohbmmadakber.shahristani@fao.org
6	Ph.Friba Nasiri	Medicine Technical Adviser	NMFB - MoPH	0796-777-178	friba.nasiri@gamil.com
7	Eng. Sayed. Naim Khalid	Food Technical Adviser	NMFB - MoPH	0773-768-295	sayednaim@outlook.com

Annex II: Membership of the Medicines Committee

No	Name	Designation	Organization	Telephone	E-mail Address
1	Ph. Abdul Hafiz Quraishi	General Director	GDPA	0799-333-930	quraishi_hafiz@yahoo.com
2	Ph. Abdul Hadi	Pharmacist	National Army Health Directorate	0799-568-092	
3	Prof. Ph. M. Shafiq Mashal	Lecturer of Faculty of Pharmacy	Kabul University	0702-216-900	msmashal@yahoo.com
4	Alhaj Abdul Khaliq Zazai	Executive officer	ANMSO	0788-405-340	anms0786@gmail.com
5	Qari Shafiullah	Director	Traditional Medicines Association	0799-067-705	
6	Ph. Fedamohammad Barin	Technical Member	HLIED	0799-306-783	
7	Ph. Amina Rustaqi	Medicine Lab manager	MoPH	0799-331-151	ksultani@gmail.com
8	Prof. S. Shershah Sadat	Lecturer of Veterinary Faculty	Kabul University	0700-057-935	sadaat-12@hotmail.com
9	Prof. Spain Jan Lalahand	Lecturer of Agriculture Faculty	Kabul University	0700-029-059	spin.jan@gmail.com
10	Ph. Razia Nazari	Member of Narcotic Board	MoCN	0797-869-367	nazari.razia@yahoo.com
11	Ph. Ab. Khalil Khakzad	Responsible of Communication and culture Commission	Pharmacist Association	0799-334-765	khalil-khakzad@yahoo.com

Annex III: Membership of the Food Committee

No	Name	Designation	Organization	Telephone	E-mail Address
1	Dr. Amanullah Hussaini	EH Director	MoPH	0700-294-312	mnlh_hussaini@yahoo.com
2	Haji Ammanuddin	Momin Group	ACCI	0700-275-942	ATIQLTD_10@yahoo.com
3	Dr. Suraya Rafa	Veterinary Doctor	MAIL	0700-169-716	sorayarafa@yahoo.com
4	Yar Mohammad Ayobi	Standard Officer	ANSA	0799-752-216	ayarmohammad@yahoo.com
5	Prof. Spin Jan Lalahand	Professor of Animal Sciences	Faculty of Agriculture, KU	0700-029-059	spin.jan@gmail.com
6	Prof. Bashir Ahmad Bashir	Professor of Biochemistry	Faculty of Pharmacy, KU	0799-264-905	bbbasherahmad@gmail.com
7	Pharmacist Basir Ahmad	Food Lab manager	MoPH	0771-070-158	basirah_faqiri@yahoo.com
8	Ahmad shah Taheri	Advisor of Export Promotions	MoCI	0700-261-473	ashah_afcart@yahoo.com
9	Abdul Wodod Nijrabi	Culture Manager	Kabul Municipality	0772-010-309	abdulwodoodnejrabi@yahoo.com
10	Sayed Zaher Maher		NEPA	0789-295-115	sayedzahermaher@gmail.com
11	Dr. Ahmad Wali Aminee	Micronutrient Consultant	MoPH - Nutrition	0700-050-741	ahmadwali_aminee@yahoo.com

Annex IV: Work Plan for the Medicines Committee of the NMFB 2012 - 2014

S/No	Reference to MC TOR	Activities	Methods of work	Responsibility	Resources required	Outputs	Period
1	Develop and revise the laws, bills & regulations related to pharmaceuticals	Develop and revise the laws, bills & regulations related to pharmaceuticals	1.1 Collect all current laws, regulations and bills related to pharmaceuticals	TA	-	Compilation of all current laws, regulations and bills related to pharmaceuticals	1 month
			1.2 Review the list of current laws, regulations and bills related to pharmaceuticals for completeness	MC	MC meeting costs	Compilation of current laws, regulations and bills reviewed by MC	1 month
			1.3 Consultancy to review all the current laws and regulations related to pharmaceuticals to identify gaps and need for revisions and development of new laws	MC	Consultancy fees	Comprehensive report on laws, bills and regulations related to pharmaceuticals Proposed legal framework for the medicines regulation	6 month
			1.4 Consultative workshop (x 1) to review report and proposed legal framework for medicines regulation	MC	Workshop costs	Consultative meeting held	2 month
			1.5 Priorities revision or development of laws based on proposed legal framework	MC	MC meetings costs	Priority list on revision of laws and regulations developed	1 month
			1.6 Establish working groups for each law and regulations that require revision or to be developed	MC	-	Working groups established based on priority list	1 month
			1.7 Consultancy and workshop (x1) on revision of laws, regulation related to pharmaceuticals	MC	Workshop, meeting & consultancy costs	Comprehensive pharmaceutical legislation	1 year
2	Develop mechanisms for ensuring the necessary capacity for the delivery of pharmaceuticals in both the public and private sectors; Provide Take a leadership role in resolving medicines-related problems and recommending	Develop and revise the guidelines and procedures related pharmaceuticals	2.1 Collect all current guidelines, rules and procedures related to regulatory activities	TA	-	Compilation of current rules, guideline and procedures	1 month
			2.2 Make current Laws, regulations, guidelines and procedures available and accessible to the stakeholders and public	MC	Printing costs	Publication of current laws, regulations, guidelines and procedures related to pharmaceuticals (1 compilation)	1 month
			2.3 Consultancy/ workshop to review and identify gaps on guidelines, rules and procedures for medicine regulatory activities (check for	MC	Workshop meeting for MC costs	Report on status of guidelines and procedures Recommendations on guidelines, procedures required in order of	1 month

S/No	Reference to MC TOR	Activities	Methods of work	Responsibility	Resources required	Outputs	Period
	interventions for the way forward		previous assessment reports and findings related to guidelines and procedures)			priority	
			2.4 Establish working groups to review and develop specific guidelines or procedures	MC	Workshop/meeting for MC costs	Working groups for development of specific guidelines or procedures established	1 month
			2.5 Consultancy / workshops on review of guidelines and / or procedures related to pharmaceutical regulation	MC	Workshop/meeting & consultancy costs	Comprehensive tools for pharmaceutical regulation developed	1 year
3	Develop mechanisms for ensuring the necessary capacity for the delivery of pharmaceuticals in both the public and private sectors;	Ensure adequate infrastructure, equipment within and outside MoPH to support regulatory activities	3.1 Familiarization tour to GDPA, National quality control laboratory, quality control laboratories at University or other Ministries or departments	MC	-	Familiarization tour conducted	3 month
			3.2 Identify and collect reports related to infrastructure, current capacity (e.g. QC testing) assessments or plans within MoPH	TA	-	List and copies of all related assessment reports related to infrastructure and equipment for GDPA the QC lab etc.	3 month
			3.3 Consultancy to review of assessment reports and government plans on infrastructure and equipment	MC	MC meetings costs & Consultancy costs	Report on current status, capacity levels and plans on infrastructure and equipment to support regulatory activities Recommendations on capacity building and infrastructure to support regulatory activities	4 month
4	Develop mechanisms for ensuring the necessary capacity for the delivery of pharmaceuticals in both the public and private sectors;	Ensure adequate human resources for medicine regulatory activities	4.1 Collect reports, organograms for GDPA, Laboratory and human resource plans	TA	-	List and copies of all HR related assessment reports, organograms, HR strategic plans	2 month
			4.2 Review of available HR situation in relation to pharmaceutical regulation	MC	MC meetings costs	Report on current pharmaceutical HR situation (regulatory)	1 month
			4.3 Development of or contribution on HR strategic plan on the regulatory component	MC	MC meetings costs	Contribution on pharmaceutical HR strategic plan on regulatory component	18 month
5	Develop mechanisms for embarking on resource mobilization for regulatory activities for medicines;	Resource mobilization	5.1 Provide input on GDPA, MoPH budget on regulatory component	MC	MC meetings costs	Submission of contributions during budget development	1 month
			5.2 List of current and potential partners with areas of potential cooperation on regulatory activities	MC	MC meetings costs	List of current and potential donors with potential areas of cooperation developed	1 month

S/No	Reference to MC TOR	Activities	Methods of work	Responsibility	Resources required	Outputs	Period
			5.3 Prepare proposals for submission to partners for support on identified gaps and needs for regulatory activities	MC	MC meetings costs	Proposals prepared and submitted to partners to support regulatory activities	1 month
6	Develop and implement mechanisms for the regulation, coordination, monitoring and evaluation (M&E) of all activities related to medicines; Coordinate all activities of the relevant stakeholders and /or authorities of the pharmaceutical industry sector;	Coordinate all activities of the relevant stakeholders for the pharmaceutical sector	6.1 List of all departments, institutions and stakeholders involved in pharmaceutical regulatory activities	TA	-	List of all departments institutions and stakeholders involved in medicine regulation developed	1 month
			6.2 Develop a filing and recording system	TA	-	Filing and recording system developed	1 month
			6.3 Consultancy to develop mechanisms for coordination, reporting and sharing information on regulatory activities; develop performance indicators for monitoring and evaluation of regulatory activities	MC	Consultancy costs	Comprehensive report with proposed recommendations on mechanism for coordination, information sharing and performance indicators	3 month
			6.4 Workshop / meeting to review consultant report on mechanisms for coordination, reporting, sharing of information and performance indicators for regulatory activities	MC	Workshop/ meeting for MC costs	Mechanisms for coordination, reporting and sharing of information developed and performance indicators developed / approved	3 month
7	Develop/Revise the Essential Medicines List (EML), Licensed Medicines List (LML)	Revise the Essential Medicines List (EML) and Licensed Medicines List (LML)	7.1 Workshop / consultancy to review the LML and EML	LML/EML Committee	Workshop meeting & consultancy costs	Draft LML/ EML developed	18 month
			7.2 Meeting to review draft LML and EML	MC	MC meeting costs	Draft LML and EML reviewed with recommendations to NMFB	18 month

Annex V: Work Plan for the Food Committee of the NMFB 2012 – 2014

FSC - Food safety component, TA -Technical Adviser of Food Affairs, CP – Chairperson of the Food Committee

Short term activities (from 3 month to 3 years)

FSC	Activities	Methods of work	Responsibility	Resources required	Outputs	Period
1 Food legislative framework (Develop/review) Laws, bills, regulations	1.1. Coordinate all activities of the relevant stakeholders for the food sector	1.1.1. List of all departments, institutions and stakeholders involved in food regulatory activities	TA		List of all departments institutions and stakeholders involved in food regulation developed	3 month
		1.1.2. Develop a filing and recording system	TA		Filing and recording system developed	4 month
		1.1.3. Workshop/ meeting to develop mechanisms for coordination of regulatory activities	CP/TA	Workshop/ meeting for MC costs	Mechanism for coordination of regulatory activities developed	6 month
		1.1.4. Workshop / meeting to develop mechanisms for reporting and sharing information on regulatory activities	CP/TA	Workshop/ meeting for MC costs	Mechanisms for reporting and sharing of information developed	6 months
		1.1.5. Workshop / meeting to develop performance indicators for monitoring and evaluation of regulatory activities	CP/TA	Workshop/ meeting for MC costs	Performance indicators developed	6 months
	1.2. Develop/Review of all existing laws, bills, and regulations concerning food, beverages and ingredients, food technology, food processing, storage, distribution and consumption, and reference standards	1.2.1. Collect and establish overall list of all existing/ drafted Laws, bills, regulations related to food products, beverages and ingredients	TA	-	Compilation of all currently drafted laws, regulations and bills related to food products, beverages and ingredients	3 month
		1.2.2. Collect and make available for FC international documents related to food, and keep them up-to-date by the means of: a) <u>electronically sources (CD Rom)</u> - library for Codex Alimentarius/FAO guidelines, manuals, codes of practice on food related matters ; b) educational <u>text books</u> on food processing, nutrition etc.	TA	Codex Alimentarius/ FAO guidelines, manuals costs	Compilation of information sources of international documents	6 month
		1.2.3. Translate few of important documents (e.g. FAO risk –based food inspection manual, FAO/WHO guide for application of risk analysis principles and procedures during food safety emergency, Codex guidelines on sampling etc.) in order to allow the FC make a better decisions on legislation formulation		Translation costs	Familiarization with international guidelines FC make a better decisions on legislation formulation	6 month 1-2 years

		1.2.4. Workshops on drafted Afghanistan Food Law and other drafted Laws, regulations	CP	Workshops costs	Consultative workshops/meetings held Familiarization with the Food Law and mandate of the competent authorities	9 month-1year
		1.2.5. Consultancy on food legislative framework	CP	Consultancy costs	Comprehensive food legislative framework	1-1,5 years
		1.2.6. Priorities review or development of laws and regulations based on proposed food legislative framework	CP	FC meetings costs	Priority list on reviewed or developed laws and regulations developed	1,5-2 years
		1.2.7. Working group on food regulation formulation for each law or regulation that require review or development	CP	-	Working groups established based on priority list	1,5-2 years
		1.2.8. Resource mobilization for regulatory activities: a) provide input on MoPH budget on food regulatory component; b) list of current and potential partners with areas of potential cooperation on regulatory activities; c) prepare proposals for submission to partners for support on identified gaps and needs for regulatory activities	CP	FC meetings costs	Submission of contributions during budget development List of current and potential partners with areas of potential cooperation on regulatory activities developed Proposals prepared and submitted to partners to support regulatory activities	1, 5-2 years
1 Food legislative framework (Develop/review) Laws, bills, regulations		1.2.9. Competent Authorities post on their Web-sites all laws and regulations of Afghanistan in force pertaining to food law	TA/CP	-	Improved communication channels to make information available for public.	1,5 years
		1.2.10. Public awareness campaign regarding new food law and budget request to the MoPH for public awareness campaign	CP	Public awareness campaign costs	Improved communication channels to make information available for public.	1,5-2 years
		1.2.11. Prepare annual Report to NMFB	CP	-	Annual report submitted to the NMFB for approval.	1 year
	1.3. Review of all existing standards, protocols and guidelines (production, transport, control)	1.3.1. Collect and establish overall list of all existing/ drafted current standards, protocols and guidelines (production, transport, control)	TA	-	Compilation of all current existing/ drafted standards, protocols and guidelines (production, transport, control)	2-2,5 years
		1.3.2. Review of existing standards, protocols and guidelines	CP	FC meetings costs	Compilation of current existing/ drafted standards, protocols and guidelines (production, transport, control) reviewed by FC	2-2,5 years
		1.3.3. Consultancy on `Review of standards,	CP	Consultancy costs	Consultancy Report on standards,	2-2,5

		protocols and guidelines relevant for Afghanistan			protocols and guidelines (production, transport, control)	years
		1.3.4. Consultative Workshop on `Review of standards, protocols and guidelines relevant for Afghanistan`	CP	Workshop costs	Consultative meeting held	2-2,5 years
		1.3.5. Working group on `Review of standards, protocols and guidelines relevant for Afghanistan`	CP	-	Working group on `Review of standards, protocols and guidelines relevant for Afghanistan` established	2-2,5 years
		1.3.6. Consultancy on `Adoption process for Codex Alimentarius`	CP	Consultancy costs	Consultancy Report on Adoption process for Codex Alimentarius	2-2,5 years
		1.3.7. Consultative Workshop on `Adoption process for Codex Alimentarius`	CP	Workshop costs	Consultative meeting held	2-2,5 years
		1.3.8. Working group on adoption process for Codex Alimentarius	CP	-	Working group on `Adoption process for Codex Alimentarius` established	2-2,5 years
1 Food legislative framework (Develop/review) Laws, bills, regulations	1.4. Adoption production standards for food storage, manufacturing and handling	1.4.1. Working groups on: a) introduction to HACCP for food production; b) specifications for food establishments; c) Training requirements and health certificates for food workers.	CP	-	Working groups established	2,5-3 years
		1.4.2. Consultative Workshops: a) introduction to HACCP for food production; b) specifications for food establishments; c) training requirements and health certificates for food workers <i>For workshops to benefit from previously drafted guidance documents produced by TAFE: (Regulations on HACCP, GMP, Sanitation Standard Operating Procedures) as a donors</i>	CP	Workshops costs	Next steps to move forward in formulation of other related regulations forming food legislative framework	2,5-3 years
2. Food control management	2.1. Development of coordination structure for food control system	2.1.1. Working group on development of coordination structure	CP	-	Working group on development of coordination structure established	2 years
		2.1.2. Consultancy `food safety and policy strategic advice`	CP	Consultancy costs	Report on proposed food safety and policy strategy	2,5 years
		2.1.3. Consultative workshops food safety and policy strategic advice`	CP	Workshops costs	Consultancy meeting held	3 years
	2.2. Development of protocols as per best practices for food	2.2.1 Working group on quality assurance at production level	CP	-	Working group established Food control system developed	2-3 years

					3. Improved capacity at the level of the food control authorities	
		2.2.2. Consultancy ` production and handling of foods conform with international guidelines and practices`	CP	Consultancy costs	Report on development of protocols as per best practices for food	3 years



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

Terms of Reference National Medicines and Food Board

22 October, 2011

National Medicine and Food Board TOR

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 center for resulting problems and challenges of this field. In response to the growing challenges of medicine and food administration and with the vested power to MoPH, in 2009 the National Medicine Board was expanded to the National Medicines and Food Board (NMFB). The mandate of the NMFB expediting reforms and coordination of efforts 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 (NMFB) 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 Dahi, MD, MPH
Acting Minister of Public Health
And NMFB Chairperson


Nov. 21. 2011

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

About SPS

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



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