ISLAMIC REPUBLIC OF AFGHANISTAN

MINISTRY OF PUBLIC HEALTH

National Medicines and Food Board

MEDICINES AND MEDICAL PRODUCTS QUALITY ASSURANCE SUB-COMMITTEE (MMQASC)

Terms of Reference (ToR) and Administrative Guidelines

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1. Background

A medicines and medical products quality assurance (QA) system can be described as the formal standards and practices which comprises the technical and management structures used by a country to manage the quality of pharmaceutical products in both the public and private sectors. This entails a systematic and orderly approach to managing the medicines quality system to ensure safety, effectiveness and efficacy.

The significance of medicines and medical products QA system lies in the ability of the National Medicines and Food Board (NMFB) of the Ministry of Public Health (MoPH) to consistently achieve set objectives through a quality management system that has been consciously established rather than evolving by chance. This requires the MoPH to view the supply chain as a complete system and a set of interrelated processes which include tasks, resources, and consistent behaviors.

In the year 2008, discussions by the MoPH with the Strengthening Pharmaceutical Systems (SPS) Program and other partners focused on quality control, which involves testing pharmaceutical samples in a laboratory. Later, the MoPH recognized that while laboratory testing is a valuable tool to ensure quality, it would be more beneficial to develop and implement a more comprehensive QA system that addresses all activities that influence the quality of pharmaceutical products, from before they enter the country until they are used by clients. This include designing an appropriate system that builds on existing capacity and a "roadmap" for how to advance the system as resources and capacity are added over time.

A comprehensive system requires involvement of multiple actors, within and outside of the MoPH and across the spectrum of public and private sectors. In the year 2008, the MoPH, with the technical support of SPS, carried out the following interventions:

- establishing medicines QA Task Force (QATF)
- planning and implementing an extensive desktop review of the pharmaceutical sectors studies
- planning and implementing a medicines screening
- planning and implementing a medicines quality assurance assessment

In the year 2009, the General Directorate of Pharmaceutical Affairs (GDPA) under the MoPH supported efforts by the QATF to advance the QA agenda and to lay the foundation for the creation of a permanent medicines QA technical committee, located within the structures of NMFB of the MoPH.

2. Justification For The Formation Of Quality Assurance Sub-Committee

In response to the growing challenges of medicines and food administration and with the vested power to the MoPH, the National Medicines Board (NMB) was expanded in 2009 to be the NMFB, which is mainly in charge of expediting reforms and coordinating efforts related to the 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 medicines items, and a rigorous control of the quality of above mentioned items.

For the efficient functioning of the NMFB, its Terms of Reference (ToR) made room for the establishment of a Medicines Committee (MC) and a Food Committee (FC) which became functional in 2012. The purpose for establishing the MC under the NMFB was to carry out in-depth technical analysis of all medicines-related issues at the national level, and make specific recommendations to the NMFB, to ensure the safety, quality, efficacy effectiveness, availability and rational use of the pharmaceutical products.

Provision was also made in the ToR of the NMFB for further establishment of any other committee or sub-committee, in which may be vested and on which may be imposed such functions of the Board as the Board determines.

One of the strategic objectives (SO-1) of the MoPH Strategic Plan 2011-2015 is to develop an effective QA system to assure the quality of pharmaceutical products in the public and private sectors. Some priority interventions, amongst others, are

(i) Establish a QA technical advisory committee;

(ii) (ii) Produce a road map for a QA methodology;

(iii) (iii) Develop, finalize and implement a 5-year QA strategy and implementation plan.[1]

In line with the foundation laid down by the GDPA and the QATF to advance the QA agenda, it became necessary to establish the Medicines and medical products QA Sub-Committee under the MC of the NMFB. This is to enable the MC assign some specific QA-related activities to the Medicine and medical products QASC to carry out expeditiously and report back to the MC for ratification and onward transmission to the NMFB for final approval and implementation. All QA activities of the Medicine and medical products QASC have therefore been aligned to the overall medicines and devices-related activities of the MC of the NMFB.

3. Objectives

The objectives of the MQASC of the MC of the NMFB are to:

i. develop and guide the implementation of national strategies for medicines QA

ii. develop and carry out advocacy for implementing the accompanying time implementation plans for medicines QA

iii. coordinate all activities related to medicines QA

iv. advise the NMFB on medicines QA-related issues through the MC

v. serve as a formal and technical interface amongst the NMFB and all stakeholders involved in medicines QA

[1] Strategic Plan for the Ministry of Public Health (2011- 2015), Government of Islamic Republic of Afghanistan. Strategic Plan (2011 - 2015). May 2011.

4. Scope of Work (SoW)

The primary responsibility of the Medicine and medical products QASC is to develop and guide the implementation of specific medicines QA-related strategic activities, assigned to it by the MC of the NMFB. Therefore, the Scope of Work (SoW) of the Medicine and medical products QASC shall be directly linked to the SoW of the MC and that of NMFB in a logical and systematic manner.

The Medicine and medical products QASC shall provide specified technical coordination and advisory services in relation to QA of pharmaceutical products and medical devices at all levels. Under the direction and guidance of the MC of the NMFB, the Medicine and medical products QASC shall carry out technical activities as assigned by the MC and in line with the priorities of the NMFB.

Any of the under-listed activities, drawn from the SoW of the MC of the NMFB, can be assigned to the Medicine and medical products QASC to carry out:

i. Develop and guide the implementation of medicines QA strategies for Afghanistan;

ii. Identify gaps related to pharmaceuticals QA and prioritizing areas for intervention to mitigate risks;

iii. Develop 1-3 year work plans for medicines QA activities based on current law, regulation and findings from available pharmaceutical QA assessments in Afghanistan;

iv. Develop a plan for implementing the 1-3 year work plan;

v. Form and assign responsibilities to working groups to carry out specific QA activities as outlined and agreed in the QA strategies and implementation plans;

vi. Follow up on tasks assigned to working groups

vii. Develop mechanisms for coordinating all medicines QA activities by the implementing bodies;

viii. Develop mechanisms for the assessment and evaluation of performance of medicines suppliers by the relevant bodies;

ix. Develop mechanisms for identifying and addressing new risks in medicines supply;

x. Develop a system for the establishment of a medicines QA surveillance system by relevant agencies ;

xi. Make recommendations regarding medicines QA to the relevant statutory and professional bodies;

xii. Develop mechanisms for developing a medicines QA communication strategy for the NMFB/MoPH;

xiii. Update and provide data and information to the major stakeholders on medicines QA issues on regular basis;

xiv. Review medicines laws, regulations, policies and master plans as necessary and make recommendations to the MC and NMFB;

xv. Review applicable medicines QA requirements and related procedures and establish mechanisms for regular updates;

xvi. Review the current registration process of pharmaceutical companies and medicines, licensing process of pharmaceutical establishments and inspection process of pharmaceutical products and establishments as necessary;

xvii. Develop standardized systems for the supply of medicines in the country: product selection, supplier selection, product certification, contract specifications, importation, inspection, targeted testing, problem reporting, storage, transportation and use of medicines;

xviii. Review the current policy and management system of the NMQCL and propose ways to make it responsive to national needs;

xix. Develop mechanisms for responding to the medicines and medical products QA surveillance reports with the corresponding corrective actions and interventions for improvement;

xx. Provide feedback as required by the NMFB, MoPH and major stakeholders;

xxi. Identify additional financial and human resources for implementing medicines QA activities;

xxii. Provide timely and accurate medicines QA reports and minutes of Medicine QASC meetings to the NMFB, MoPH and development partners as necessary;

xxiii. Maintain records of proceedings and actions of the Medicine and medical products QASC

xxiv. Carry out any other medicines QA-related activities as may be assigned by the NMFB or the Minister for Public Health.

5. Composition

The members of the Medicine and medical products QASC shall be selected from major agencies, stakeholders of the pharmaceutical sector, consistent with the NMFB ToR. The Medicine QASC shall consist of a minimum of three (3) and maximum of six (6) members, and at least one person who is a member of the Board. The Medicine QASC members shall be selected from the agencies/organizations as below:

i. One representative from the GDPA

ii. One representative from the LIED

iii. One representative from the NQCL

iv. One representative from the Faculty of Pharmacy

v. One representative from Kabul Medical University

vi. One representative from Pharmaceutical Associations

The QASC may co-opt any other person who can make significant technical contribution to the work of the QASC, subject to the final approval of the NMFB through the MC. The co-opted members shall be selected from the agencies/organizations as below:

i. One representative from the Afghanistan National Standard Authority (ANSA)

ii. One representative from the WHO.

6. Selection of Medicine and medical products QASC Chairman

In accordance with the NMFB ToR, the QASC shall be chaired by a member of the Board. Consistent with the meeting procedures as stated in the NMFB ToR, the selection of the QASC Chairperson by the Board shall be by a simple majority vote at a meeting of the Board at which a quorum is present.

7. Selection of medicine and medical products QASC Members

All six (6) members appointed to the Medicine and medical products QASC shall have at least five (5) years of professional experience or familiarization with the relevant laws and policies, consistent with the NMFB ToR.

Additional in-depth knowledge in any of the following areas is an advantage for selection: (i) Pharmaceutical and medical device technology and manufacturing; (ii) Pharmaceutical chemistry and analytical techniques; (iii) Pharmacology and therapeutics; and/or (iv) Regulatory and management of pharmaceutical affairs.

All Medicine and medical products QASC members must be officially nominated and/or approved by their respective agencies or organizations for subsequent approval by the NMFB.

8. Roles and Responsibilities Medicine and medical products QASC Chairperson

The Chairperson of the QASC shall guide all meetings, endorse all decisions by signing the adopted minutes, be present in meetings and decision making (to the extent possible), expedite and follow up the implementation of decisions made by the MQASC.

9. Roles and Responsibilities of Medicine and medical products QASC Members

All members of the Medicine and medical products QASC shall attend meetings regularly, be punctual to meetings, participate actively in all meetings, make decisions to address medicines-related issues, collect the necessary information on various technical issues to be discussed by the QASC, contribute actively in developing the necessary documents for the improvement of medicines-related issues, and participate in monitoring activities of the MQASC.

10. Secretariat Responsibility

The Secretariat of the NMFB shall be responsible for the coordination of the administrative, financial and technical functions of the Medicine and medical products QASC. The Secretariat shall notify the members of the QASC of meetings and ensure that minutes of meetings and agenda are prepared and circulated in advance to members.

11. Tenure of Office

A member of the Medicine and medical products QASC shall hold office for such period as may be determined by the NMFB. A member may be eligible for re-appointment by the NMFB if his/her organization re-nominates him/her, and the MC endorses the re-nomination.

A member may be expelled from the Medicine and medical products QASC upon three consecutive absences from sub-committee meetings without prior notification, and non-compliance with accepted standards of the NMFB. A member of the MQASC who is convicted of any crime by a court of competent jurisdiction shall cease to be a member.

12. Operating Principles medicine and medical products QASC

A member of the Medicine and medical products QASC shall consider the interest of the country above his/her personal activities. The MQASC shall be professional, transparent, impartial, independent and timely in its discussions and recommendations to the MC, NMFB and the Hon. Minister of Health as appropriate.

13. Withdrawal from the Medicine and medical products QASC

Any MQASC member who is unable to attend a meeting shall notify the Medicine and medical products QASC Chairperson or NMFB Secretariat in advance. Any member who absents him/herself from meetings for three consecutive times without any tangible reason shall be deemed withdrawn from the medicine and medical products QASC. Absent is defined as not participating in a meeting physically or by teleconference.

The medicine and medical products QASC Chairperson has the discretion to approve in advance an extended absence of any member. Other members shall be informed of such extension. An individual may resign as a member at any time upon written notification to the medicine and medical products QASC Chairperson, who shall accordingly inform the NMFB, through the MC.

Any medicine and medical products QASC member who reveals confidential information or takes undue advantage of his/her membership, or misconducts him/herself at a meeting, may lose his/her membership as decided by the medicine and medical products QASC and approved by the MC.

In case a member of the medicine and medical products QASC forfeits his/her membership for any reason, the agency or organization concerned shall be duly notified and requested to nominate another representative for consideration by the NMFB.

14. Logistical Support

The NMFB/MoPH shall be responsible for providing the necessary human resource and logistical support to the Medicine and medical products QASC for its efficient function. The Medicine and medical products QASC Chairperson, with support from members, shall ensure that all assets, records, papers, books, documents and instruments provided by the NMFB for the functions of the Medicine and medical products QASC are well kept and readily available at all times.

15. Accountability and Responsibility

The Medicine and medical products QASC shall ultimately be accountable and responsible to the NMFB, through the MC. The activities of the Medicine and medical products QASC shall be monitored and evaluated regularly and periodically by the MC, and progress reports shall be submitted to the NMFB through the MC. The Medicine and medical products QASC shall be obliged to provide reasonable explanations for targets not met, as may be requested by the MC or NMFB. Such requests shall be made in writing to the Medicine and medical products QASC Chairperson through the MC, copied to the Office of the Hon. Minister for Public Health.

The MQASC shall prepare and submit quarterly and annual reports to the MC. The MQASC shall also prepare and submit any other report on any special issue as may be requested by the MC in writing. Such reports shall contain all the necessary details, leaving no room for ambiguity.

16. Meetings

The Medicine and medical products QASC meetings shall be a formal platform for national and international issues related to the QA of medicines. The frequency of Medicine and medical products QASC meetings shall be determined by the MC based on volume of work to be done. Extra-ordinary Medicine and medical products QASC meetings may be held at the request of the MC Chairperson or Medicine and medical products QASC Chairperson.

Topics on the agenda of the MQASC shall be directly linked to its SoW, as assigned by the MC. It is the responsibility of the NMFB/MoPH to ensure that the MQASC functions properly and fully.

The meeting modalities of the MQASC shall be agreed upon by all members. With the consent of the MQASC Chairperson, any MQASC member may participate in a meeting by means of teleconference or other communication equipment through which all persons participating in the meeting can hear each other well.

The MQASC members shall agree on a location for its regular meetings. However, meetings of the MQASC may be held at such locations and times as may be determined by the MQASC Chairperson or Hon Minister for Public Health, as the case may be. Such locations shall be communicated in good time to all members via their regular e-mail addresses and telephone numbers.

17. Notice of Meetings

Notice of time, location and agenda for all Medicine and medical products QASC meetings shall be served on Medicine and medical products QASC members at least one week prior to the date of the scheduled meeting. In case of an extra-ordinary meeting, notice shall be served on Medicine and medical products QASC members in reasonable time before the meeting date. All official notices shall be served by official letter, e-mail addresses and/or telephone numbers provided by Medicine and medical products QASC members. Other communication channels may be used as support or confirmation of notices of meetings as necessary. Photocopies of all necessary materials may be made available to members at all meetings.

In the event of cancellation of a scheduled meeting, the NMFB Secretariat shall ensure that all Medicine and medical products QASC members are served notices of the cancellation, followed up with telephone calls.

18. Meeting Quorum

The quorum for Medicine and medical products QASC meetings shall be two thirds ($^2/_3$) of its entire membership (including co-opted members). All meetings must start on time, once the quorum requirements are met. If after one hour of the scheduled time for a meeting there is no quorum, the meeting shall be adjourned till further notice.

If later in the course of a meeting the number of Medicine and medical products QASC members present falls below the quorum requirements, normal business shall continue until such time that a member raises an objection. Issues discussed in such instance shall be ratified at the next Medicine and medical products QASC meeting.

In the absence of the Medicine and medical products QASC Chairperson, any member shall be elected to chair the meeting, except that any Board member present shall be given preference as Chairperson of the meeting. All decisions of the Medicine and medical products QASC are deemed conclusive and binding, after ratification by the MC.

19. Voting at Meetings

At all Medicine and medical products QASC meetings, any motion may be decided upon by a simple majority of members (including co-opted members) present and voting or by consensus. Voting may be by a show of hands, unless circumstances require balloting. The identity of the voters may not be recorded. However, a member may require that his/her opinion and vote be recorded in the minutes. At all Medicine and medical products QASC meetings, each member present shall have one vote on an issue before the MQASC. In the event of a tie during voting, the Chairperson of the meeting at that time shall have a casting vote.

20. Minutes of Meetings

The NMFB Secretariat shall ensure that minutes of the Medicine and medical products QASC meetings are served on all members, regardless of whether they were at the meeting or not. Names of the persons present shall be entered in the minutes. All minutes shall be read, corrected and approved at the subsequent Medicine and medical products QASC meeting. Records of meetings shall be an accurate reflection of the actual motions, resolutions and results of deliberations and decisions of the Medicine and medical

products QASC. The final minutes shall be signed by the MQASC Chairperson, and filed accordingly. Feedback from the NMFB on the Medicine and medical products QASC minutes shall be discussed and recorded accordingly.

21. Conflict of Interest

Before accepting any appointment to be a member of the Medicine and medical products QASC, a member shall disclose any potential conflicts of interest. Potential or actual conflicts of interest by members of the Medicine and medical products QASC shall be identified and declared or disclosed to the MC.

A member ofMedicine and medical products QASC with conflict of interest or potential conflict of interest shall not take part in the consideration or discussion of or vote on any issue before the Medicine and medical products QASC, for any issue in which he/she or spouse has substantial interest in the matter. If not declared, any other person who is aware of the issue shall inform the Medicine and medical products QASC Chairperson or MC Chairperson accordingly for action to be taken. If it is not clear whether or not a conflict of interest exists, the issues shall be brought before the NMFB which shall make a final decision.

An obvious conflict of interest may arise, if a member or his/her own family would benefit financially from his position of power. This may occur through the award of a contract to a company, agency or organization to which he/she belongs or is owned by a relative.

On the other hand, it would not be illegal to award a contract to the best qualified company, agency or organization even if that were indeed owned by a relative, but the member should not be part of that particular decision making process. Members must disclose areas of potential conflict of interest.

22. Confidentiality Agreement

All Medicine and medical products QASC shall sign a confidentiality agreement at the time of appointment. Decisions and recommendations of the Medicine and medical products QASC shall remain confidential, and no member other than officially designated person(s) shall disclose to any other person the decisions and recommendations of the Medicine and medical products QASC or MC on any issue undergoing discussions. Any Medicine and medical products QASC member who violates the rules and regulations of the NMFB shall be subject to penalty as may be determined by the MC, NMFB or the Hon Minister of Public Health.

23. Collaboration with Relevant Stakeholders

For the optimal resource utilization and avoidance of duplication, the Medicine and medical products QASC shall, through the NMFB mechanisms, establish and maintain close collaboration with all relevant stakeholders in medicines QA affairs.

24. Remuneration of Members

The Medicine and medical products QASC members, including co-opted members, who are public servants and non-employees of international donor partners, shall be paid such

allowances/incentives as the Hon. Minister of Public Health, in consultation with the NMFB, may determine.

All other persons whose services are approved by the NMFB and utilized by the Medicine and medical products QASC shall be remunerated accordingly, upon satisfactory completion of their assignments. The payment of allowances shall be subject to availability of funds for such purposes.

25. Indemnification of Members

The NMFB/MoPH indemnifies all Medicine and medical products QASC members, including co-opted members, against any claims, expenses or liabilities that may be incurred by any person by reason of being or having been a member. The indemnity applies only in the period during which the member was actually serving on the Medicine and medical products QASC of the MC of the NMFB.

26. Effective Date of Enforcement

The foregoing ToR and Administrative Guidelines of the Medicine and medical products QASC of the MC of the NMFB shall come into effect from the date of approval by the Hon. Minister of Public Health and NMFB Chairperson, and shall remain effective for the entire life of the NMFB.

APPROVED BY:

HON. DR. SURAYA DALIL

MINISTER OF MOPH AND NMFB CHAIRPERSON