Islamic Republic of Afghanistan

Ministry of Public Health

CONCEPT NOTE
National Medicines & Healthcare Products Regulatory Authority

December, 2015

Contents

List of Acronyms

ADR	Adverse drug reaction
ASIA	Afghan Investment Support Agency
CBR	Capacity Building for Results
EML	Essential medicines list
GDPA	General Directorate of Pharmaceutical Affairs
GDPS	General Directorate of Pharmaceutical Services
GMP	Good manufacturing practices
HLIED	Health Legislation Implementation Ensuring Directorate
IT	Information technology
LML	Licensed medicines list
M&E	Monitoring and evaluation
MFQCD	Medicines and Food Quality Control Directorate
MoPH	Ministry of Public Health
NMFB	National Medicine and Food Board
NMHRA	National Medicines and Healthcare Product Regulatory Authority
PMIS	Pharmaceutical management information system
SPS	Strengthening Pharmaceutical Systems
WHO	World Health Organization

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1. Background

Afghanistan is a country where the quality of the pharmaceutical products has been criticized by the citizens and consumers, and where, due to the long and uncontrollable border lines with Pakistan and Iran, huge amount of illegal, counterfeit, and sub-standard medicines are being imported into the country. Informal evidence shows that huge volumes of medicines are being produced illegally outside the borders specifically for export to Afghanistan. The medicines which are illegally imported are never tested for quality, thus they are not being controlled in a proper and standard manner after being supplied to the market.

Unofficial data show that smuggled medicines available in the market account for up to 40% to 55% of the total medicine in the market. Furthermore, the national licensed medicine list (LML) includes 1,800 medicine items, but many of the medicines present in the market are not included on the LML. This necessitates a regular amendment of the national LML and accurate and regular market controls.

The data indicate that more than 95% of the imported medicines in Afghanistan come from Pakistan, Iran, India, and central Asia. More than 1,090 medicine importation companies have been registered at the Ministry of Public Health (MoPH), 238 of which are actively operating. These companies import medicine and health products for public and private sectors, but the quality of the imported medicines by these companies needs to be standardized. In addition, more than 14,000 drugstores exist across Afghanistan, 3,000 of which are located in Kabul city.

In Afghanistan, the medicine and health product sector has been organized in a way which is not responsive to the current needs. The main problems in the medicine sector include poor management, conflict of interest, influence of the private sector in decision-making, insufficient funds and human resources, low salaries, lack of focus on quality, interference in duty and uncertainty of an accountable body, and shortage of infrastructure and required resources for the enforcement of laws and regulations. For instance, currently the inspection of importation companies, manufacturing factories, medical stores, and certain relevant establishments is being carried out by General Directorate of Pharmaceutical Affairs (GDPA), Health Legislation Implementation Ensuring Directorate (HLIED), and the Monitoring and Evaluation (M&E) Directorate. At the same time, quality control activities are undertaken by the Medicine and Food Quality Control Directorate (MFQCD), while the National Medicine and Food Board (NMFB) operates as medicine and food monitoring board sectors within the MoPH. Several entities are involved in the regulatory activities in a parallel and uncoordinated manner, which has led to poor management in the pharmaceutical sector.

Taking these needs into account, cohesion of current structures and establishment of an independent and responsive National Medicine and Healthcare Product Regulatory Authority (NMHRA) is considered a critical step towards the improvement of pharmaceutical affairs. The establishment of this authority, staffed by capable personnel with clear responsibilities, will prove advantageous in ensuring people's access to safe, effective, quality, and affordable medicine and healthcare products.

This document aims to present a concept for the establishment of an independent NMHRA in the country, through which the regulatory activities of various MoPH authorities are coordinated and incorporated so that it is ensured that medical products are of a better quality and that the medicines consumed in the country are safe.

2. Model Used for the Development of this Concept

The models for pharmaceutical affairs regulatory authorities at the international level are largely similar; all the countries have tried their best to practice and implement the World Health Organization (WHO) guidelines. According to the WHO guidelines, the medicine regulatory authorities shall consist of six sections (namely licensing, inspection and regulations enforcement, quality control, product evaluation and registration, promotion and advertisement control, and pharmacovigilance or scientific monitoring of medicine safety and effectiveness). In addition, WHO recommends that factors such as autonomy, sufficient coordination, and freedom from political and business influence, sustainable financial mechanisms, competent human resources, transparent policies and working practices, and results-based performances can ensure the effectiveness of medicine regulatory authorities.

In 2002, WHO published an assessment study in regard to the pharmaceutical affairs regulatory authorities of 10 countries: Estonia, Uganda, Cyprus, Malaysia, Venezuela, Zimbabwe, Australia, Holland, Cuba, and Tunisia.

This study shows that 70% of these countries undertake regulatory activities through the regulatory authorities which include development of regulations; inspection of establishments; issuance of license to manufacturing establishments; study and registration of products; importation control; quality control; medicine promotion and advertisement control; and issuance of license to importation, retail, and wholesale establishments. Generally, in most of the countries under assessment, the national pharmaceutical affairs regulatory authority does not perform non-regulatory duties. It's worth mentioning that the price of medicine in 20% of the countries (e.g., Cyprus and Tunisia) is being control by their national medicine regulatory authority.

In 60% of the cases, the medicines regulatory authority is entitled to the power to recruit and dismiss its personnel, and these authorities are financially fully or partially independent from government. Some of these authorities are funded only through receipt of fees (e.g., Zimbabwe and Australia), and some of the authorities are only funded by the government budget (e.g., Uganda). At the same time, most of the medicines regulatory authorities make use of the combination of above-mentioned two sources of finances. From among the 10 countries, only Australia, Uganda, and Zimbabwe have full autonomy to manage their budgets. While, Malaysia and Venezuela add the fees they charge in return to the services in the government treasury, this way the annual budget will be allocated to them, and the regulatory authorities in these countries have no financial autonomy. In all the countries under assessment, common legislative and structural factors exist where all the pharmaceutical affairs regulatory authorities belong to the government.

In addition to these 10 countries, the models used in other countries are almost the same. The medicine regulatory authority of Pakistan was established in 2012. It is an independent authority and under the managerial control of the federal government based in Islamabad with sub-offices in various states of this country, and it consists of an executive director and 13 section directors. It also has policy board responsible for developing policies and guidelines, monitoring operations, determining fees, allocating budgets, and establishing expert and appeal committees. This regulatory authority also consists of departments such as medicine study and registration, license issuance, quality assurance and laboratory tests, medical products and cosmetics, biologic medicine, medicines under control (e.g., anesthesia drugs), vaccination, medicine services, traditional medicine, pricing, budget and accounting, administration, human resources and logistics, legislative affairs, and information management.

In most of the countries (such as Iran, the United States, Sudan, and Tanzania), the medicine regulatory authority and food regulatory authority are incorporated and only one regulatory authority manages both of the sections. In other countries (such as in India), numerous regulatory authorities operate in this regard.

3. Model Used for Setting Duties

With regard to NMHRA duties, MoPH has taken into consideration the experiences of and structures in many countries and the recommendations of WHO, and made use of the WHO-recommended model for this proposed concept. Those duties are licensing, inspection and regulations enforcement, quality control, product evaluation and registration, promotion and advertisement control, and pharmacovigilance or scientific monitoring of medicine safety and effectiveness. The departments are also planned as per the WHO-recommended duties. These duties are common for all the regulatory authorities in all the countries reviewed (table 1).

Table 1: Regulatory activities performed by the medicine and health product regulatory authorities in various countries

Duties	Afghanistan*	England	Pakistan	Australia	Cuba	Cyprus	Estonia	Malaysia	New Zeeland	Tunisia	Uganda	Venezuela	Zimbabwe
Production license	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
License and control of imports	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Wholesale license	✓	✓	✓	×	×	×	✓	✓	✓	✓	✓	✓	✓
Retail license	✓	✓	✓	×	×	✓	✓	✓	×	✓	✓	✓	✓
Products assessment and registration	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Audit of good methods of production	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Audit of distribution channels	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	✓
Product quality control	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Promotions and advertisements control	✓	✓	✓	✓	×	✓	✓	✓	✓	✓	✓	✓	✓
Price control	✓	✓	✓	×	×	✓	×	×	×	✓	×	×	×
Prescription control	✓	×	×	✓	✓	×	✓	✓	×	×	×	✓	✓

* = Proposed by Afghanistan, ✓=Yes, ×=No

3.1. Model Used for Determining Managerial System and Funding Sources

From the structure perspective, the managerial system of the proposed model is similar to that of the numerous countries, in particular, England. In England the Medicine and Health Product Regulatory Authority is an executive department of Health Ministry, regulating the pharmaceutical affairs and medical equipment. This authority has a board assigned with the duty of monitoring the authority's implementation of strategic objectives, and counseling the authority. This board was established to ensure further transparency, technical expertise and enrichment, and resource mobilization.

From the funding aspect, the proposed Afghanistan model will be similar to that of countries like Pakistan, Uganda, and some other countries that are funded from government resources, accumulated fees in return for services, or grants.

In the development of this concept and due to the limited financial resources in the country, efforts have been made to propose the fewest possible organizational structures. For instance, in most of

the countries reviewed, the departments of general medicine, biologic medicine, traditional medicine, and medicine under control are established separately, but in this proposed concept each organizational unit of this authority will handle all the medicine categories according to their scope of work and in a coordinated manner. For example, the monitoring and registration department will evaluate all groups of medicines and will register them in the database.

The proposed name for this authority is adapted from the one in England, adding the word "National." The National Medicine and Healthcare Product Regulatory Authority in Afghanistan will be a General Directorate in the organizational structure of MoPH.

In the future and with the help of WHO, efforts will be made for NMHRA to sign a cooperative agreement with one of the successful medicine and health product regulatory authority at both country and regional levels, so that the authorities can exchange and learn from each other's experiences and improve the quality of the proposed authority in Afghanistan.

For further detailed information on the circumstances of the proposed authority and funding sources of authorities in other countries, please refer to table 2. The creation of this regulatory authority is an internationally accepted requirement and necessity, and the majority of the countries taking into account WHO's recommendations have been successful in establishing this agency.

Table 2: Place of regulatory authorities and their autonomy and funding circumstances

	Specification						
	Reporting source	**Autonomy on appointment and dismissal of employees**	**Financial freedom**	**Performing non-regulatory duties**	**Specified budget for medicine regulation**	**Funding sources (percentage)**	**Fee against services**
Afghanistan*	Health ministry	✓	Partially	×	✓	Government Fee Grant	✓
England	Health department	✓	✓	×	✓	Government Fee	✓
Pakistan	Health department	Not received	✓	×	✓	Government Fee Grant	✓
Australia	Health department	✓	✓	×	✓	Fee	✓
Cuba	Health department	×	Partially	×	✓	Government Fee Grant	✓
Cyprus	Health department	×	Not received	Procurement and production	×	Government budget	✓
Estonia	Health department	✓	Partially	×	×	Government Fee Grant	✓
Malaysia	Health department	×	×	Managing hospitals	✓	Government budget	✓
New Zealand	Health department	✓	✓	×	✓	Fees	✓
Tunisia	Health department	×	×	×	×	Government budget	✓
Uganda	Health department	✓	✓	×	✓	Government Fee Grant	✓
Venezuela	Health department	✓	×	Biological products	✓	Government budget	✓
Zimbabwe	Health department	✓	✓	×	✓	Fee	✓

4. Vision, Mission, and Objectives

The proposed NMHRA in Afghanistan has the following vision, mission, and objectives.

Vision*:* Availability of safe, efficacious, quality, and affordable medicines and health products for all Afghans.

Mission*:* To ensure access to quality, safe, and effective medicines and health products through regulation and control of production, importation, exportation, distribution, and use.

Objective: To develop and enforce effective standards in order to optimize the safety, efficacy, quality, and affordability of medicines and health products throughout the country. This regulatory authority has the following specific objectives:

1. Design, development, and review of laws and regulations, particularly in regard to manufacturing, importation, and issuance of medicine and health products
2. Integration and improvement of process of license issuance to establishments and pharmacists
3. Inspection and enforcement of laws and regulation on medicine and health products in the market through integration and regular review
4. Ensuring the quality of manufactured and imported medicine and health products through standard laboratory tests
5. Regular registration of medicine and medical products, and creation of pharmacovigilance system
6. Promotion and advertisement control of medicine and health products to ensure proper information dissemination to the citizens
7. Improvement of operations through transparency and reduction of administrative corruption

Objective 1: Design, development, and review of laws and regulations, particularly in regard to manufacturing, importation, and issuance of medicine and health products

Strategy to achieve the first objective: The different sections in the MoPH departments that are busy in design and development of laws and regulations in regard to medicine and health product market creation will be incorporated and created through a unified source of regulatory document. This way, not only the duplication of documents and executive operations will dissolve, but the defects and variance in the documents and processes will also be prevented.

Secondly, all the internal experts will get together, and international capacities (particularly the WHO) will be utilized. The expert committee consisting of the Ministry cadres, specialists from outside the Ministry, and international colleagues will be assigned and given specific terms of reference (ToR).

Thirdly, all the existing regulatory documents will be reviewed. After considering the international experiences and national needs, these regulations will be reformed as needed. The process will be advisory, and law and regulation will be revised based on the criteria like effectiveness, quality, transparency facilities, coordination with other national and international laws, applicability to implementation, and comprehensiveness.

Fourthly, after the consultations and necessary approvals, the regulatory documents will be made widely accessible to stakeholders through mass media outlets such as publications, electronic posts, websites, and training programs. Additionally, a copy of the regulatory documents will be made

available in the information section of the mentioned authority as a single source for those in need of its access.

Efforts will be made to schedule the assessment of the regulations so necessary improvements can be made in a timely manner.

Objective 2: Integration and improvement of process of license issuance to establishments and pharmacists

Strategy to achieve the second objective: Firstly, all the parallel authorities of public health in the area of issuance of licenses to establishments and pharmacists will come under one unified authority, and then a single license issuing authority will be assigned according to the proposed organizational structure.

Secondly, all the licensing guidelines and standards will be reviewed and adjusted according to the internationally agreed upon standards and national needs. To define standards and develop guidelines for licensing, technical assistance will be sought from WHO.

Thirdly, clear, transparent, and easy procedures will be developed for all the processes of issuing licenses to establishments and pharmacists. To the extent possible, efforts will be made to simplify the license issuance to the national manufacturing companies so that investment opportunities in domestic production are further facilitated. Additionally, the standards and process of license continuation will also be defined and executed based on the time and regular conformity of pharmaceutical establishment with the qualitative standards.

For further easy access, a copy of the guideline on obtaining licenses will be made available on the website and at the information office.

The licensing information registration system will be promoted to the electronic system, and, in cases deemed necessary, there will be an exchange of information with the Ministry of Commerce and the Afghan Investment Support Agency (AISA). The monitoring indicators regarding the timely issuance of licenses will be added to the performance monitoring framework of the mentioned authority in accordance with the guidelines, and will be followed up on regularly.

All of the existing licenses issued to manufacturing and importation companies will be reviewed and adjusted according to the new guidelines. Any license not meeting the mentioned standards will be negated according to the rules.

Objective 3: Inspection and enforcement of laws and regulation on medicine and health products in the market through integration and regular review

Strategy to achieve the third objective: Firstly, all the individuals and capacities from various MoPH units that monitor and evaluate medicines and health products in the market will be brought under one unified unit.

The existing strategy on development of a monitoring checklist (for assessing various establishments, including importation companies, manufacturing factories, medicine warehouses, medical stores, and wholesalers) will be reviewed and electronic databases will be created to follow up on the operations and to monitor the general situations. In addition to this, effective monitoring and evaluation guidelines and guidelines for using the monitoring and evaluation checklists will also be developed, and related trainings will be conducted for relevant personnel.

Kabul has 3,000 medical stores; for practical reasons, these have been divided into clusters based on geography and distribution. For every 50 to 60 establishments, one monitoring officer is assigned to carry out a comprehensive monitoring each quarter; the practical monitoring will take place in a group. Every establishment will be monitored at least once in each quarter. The focus of the monitoring activities will be on priorities such as counterfeit or illegal medicine. In order to follow up on the monitoring findings, a written commitment to a corrective plan will be taken from the establishment and followed up on during subsequent monitoring visits.

The proposed NMHRA will be equipped with the required facilities including transportation. The monitoring indicators will be defined and published as a quarterly report. In the monitoring and evaluation visits, efforts will be made to meaningfully engage private-sector representatives (particularly representatives of relevant unions), to ensure their full understanding of the requirements and to encourage the private sector to incorporate quality improvement through their own internal processes.

Findings from the monitoring teams will be followed up on regularly and, according to the rules, disciplinary actions or incentive-driven actions will be enforced.

Objective 4: Ensuring the quality of manufactured and imported medicine and health products through standard laboratory tests

Strategy to achieve the fourth objective: To achieve the fourth objective, the laboratory on quality control of medicine and health products will be strengthened and improved. Therefore, provision of a suitable facility, necessary equipment, and trained personnel, and a review of the process to accelerate the implementation and procedures development will be priorities. Furthermore, this laboratory, with the cooperation of WHO, will be linked to a reference laboratory in order to ensure better quality.

The registration process and reporting systems will be facilitated and promoted to electronic systems. During the last few months, actions have been taken in regard to the strengthening of the mentioned laboratory and will be followed up vigorously. In the next phases, considering the financial and technical elements, focus will be drawn on the quality control laboratories at the port-linked provinces in the country. These laboratories could be expanded independently, by the government, or in collaboration with the private sector, albeit not providing room for any conflict of interest.

Objective 5: Regular registration of medicine and medical products, and creation of pharmacovigilance system

Strategy to achieve the fifth objective: In accordance with the WHO standards, all the manufacturing and importation items will be registered after their assessment and distribution points. In the next phases, the guidelines on pharmacovigilance or adverse drug reaction (ADR) assessment systems will be developed, linking them with hospital-related clinical systems. In addition, adverse reactions reported to be the result of vaccinations will be scientifically assessed and shared with the relevant sources. This issue is of high importance to the MoPH because these concerns are often unfounded, yet could decrease vaccination rates and have negative consequences.

The relevant personnel will be given required training (on pharmacovigilance/ADR reporting) and the ADR electronic registration system will be developed. ADR reports will be shared at the international level (Uppsala Monitoring Center) to be properly evaluated with other countries' reports and

scientific evidence, thus ensuring that the medicines and ADRs are thoroughly studied from all angles. In case of resistance against a medicine or emergence of adverse reactions, actions will be taken according to the WHO guidelines.

Objective 6: Promotion and advertisement control of medicine and health products to ensure proper information dissemination to the citizens

Strategy to achieve the sixth objective: The first step towards controlling nonscientific promotion of medicines will be to transfer the mentioned unit from the General Directorate of Pharmaceutical Affairs to medicine and health products regulatory authority.

Guidelines on designing promotions and advertisements have been prepared; these will be provided to all stakeholders, including private sector unions, importation companies, and manufacturing enterprises. In the new law on medicine and health products, irresponsible and nonscientific advertisements will be banned, and the promotions and advertisements approval mechanism will be designed and operated with the cooperation of Ministry of Information and Culture. The regulatory authority will manage the approval mechanism, which will review advertisements before they are broadcast. Nonscientific print advertisements in the city will be followed up on, and prevented by the monitoring teams, in accordance with the laws and regulations.

Objective 7: Improvement of operations through transparency and reduction of administrative corruption

Strategy to achieve seventh objective: The NMHRA will bring all relevant activities of different MoPH departments together under one umbrella, and will be recognized as the single authoritative and responsible source in systematizing the pharmaceutical sector in Afghanistan. The terms of reference of this entity and its subordinate sections are developed in a way that clearly reflects roles and activities, thus work duplication will not emerge. In addition, the areas of cooperation and coordination mechanisms from the board level to the executive directorate level at this entity have been developed.

Executive procedures in different sections of this entity need to be developed, and the personnel will be given necessary trainings on laws, regulations, and procedures. The financial technical audit system will be established and assessed according to the entity's technical and financial action plan.

The executive director will be made responsible to the board and the subordinate departments will be accountable to the executive director through terms of reference, plans, and performance assessments. Additionally, a culture of offering rewards for good work and taking disciplinary actions when needed will be developed and practiced in this entity.

Considering the importance and range of potential complaints, the complaints office of the regulatory authority will address complaints received from within or without (e.g., the manufacturing or importation companies), either by itself or through the board. A complaint redressal mechanism will be established to follow up on the complaints, the indicator for which has already been reflected in the entity's monitoring framework of operations.

The annual work assessment of this entity has been included in the annual plan; according to its findings, actions will be taken for the further improvements of its activities.

5. Leadership and Organizational Structure

The NMHRA will implement all the principles of good governance in the area of pharmaceuticals, as defined by the WHO. The NMHRA will operate based on the following organizational structure:

5.1. National Medicine and Health Product Independent Board (Governance Board)

The National Medicine and Health Product Board, under the directorship of the minister of public health as the high board, will operate in the area of development and implementation of relevant policies, and monitoring the NMHRA's strategic activities.

The board will specifically undertake the following duties:

- Advise the MoPH and Presidential Office on appointment and dismissal of NMHRA executive director
- Approval of policies, strategies, and guidelines
- Support to NMHRA in regard to legal and budgetary issues, and coordination with different governmental and nongovernmental organizations
- Advising on standardizing the administrative and financial affairs reporting system; approving financial accounts and annual reports of the entity
- Cooperation in ensuring transparency in the entity through advising on establishment of an effective internal audit mechanism and certain other relevant mechanisms
- Approval of and delivering advice on initiatives and new strategies, as well as on establishment of sub-committees as required
- Advising on developing plans and monitoring of implementation these plans, and ensuring corrective action as required and/or necessary
- Advising on developing effective internal and external communications policy, and monitoring its implementation

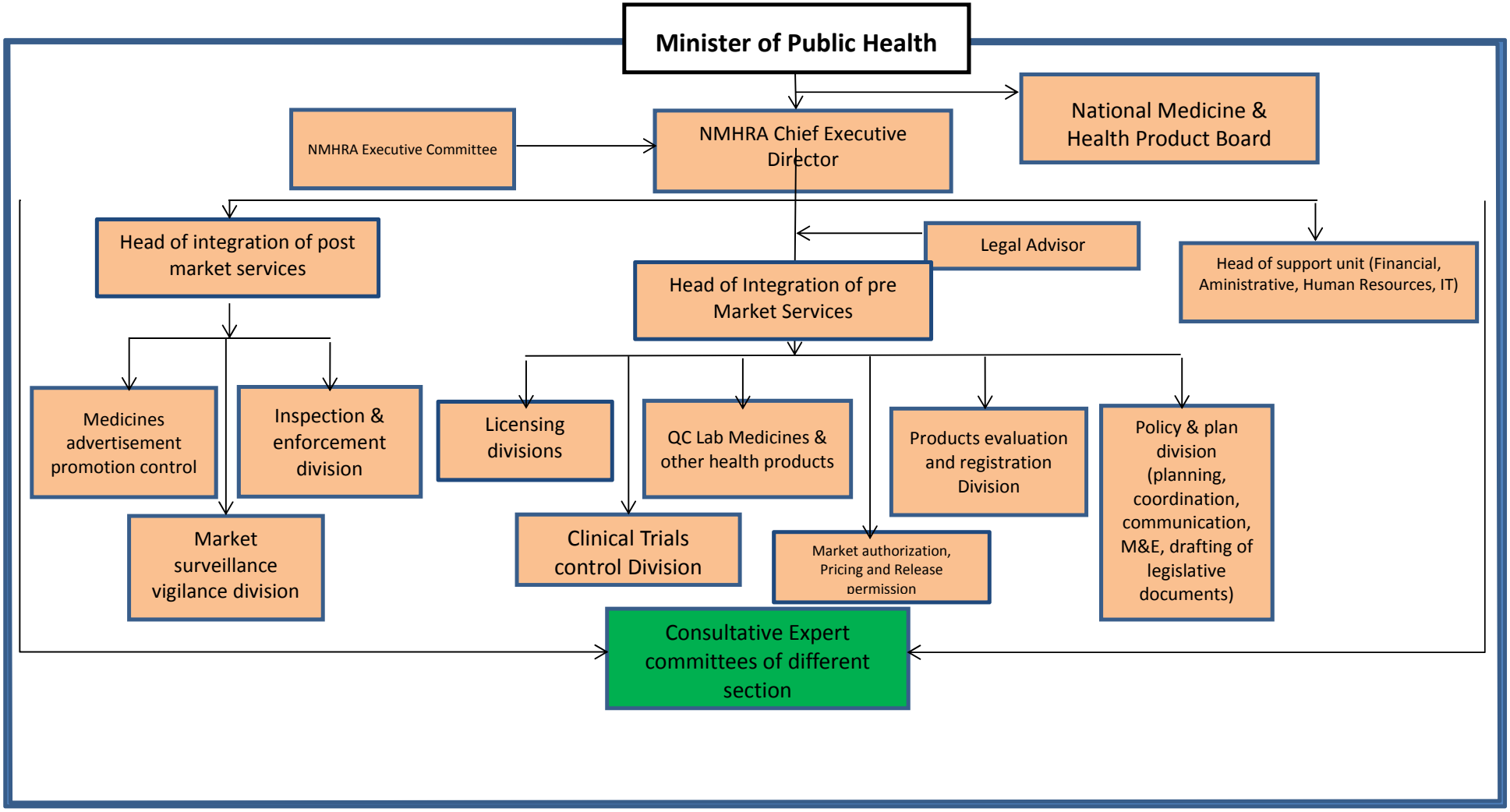
The National Medicine and Health Product Board consists of the following designations, while in case there is need for more members, the board can decide accordingly:

1. Minister of public health as the head
2. One representative from Afghan National Standard Authority
3. One representative from Pharmacology Department of Kabul Medical University
4. One representative from Faculty of Pharmacy, Kabul University
5. One representative from Directorate of Veterinary Ministry of Agriculture
6. One representative from Office of the President
7. One representative from pharmacists' association
8. One representative from WHO
9. Head of National Medicine and Healthcare Product Regulatory Authority
10. One representative from importation companies association (no right to vote)
11. One representative from manufacturing companies union (no right to vote)

5.2. Structure and Circumstances of Appointing the Chief Executive Director of NMHRA

The proposed structure of the NMHRA has been arranged based on the list of the duties it should perform. The executive director of NMHRA will be appointed with the consultation from the board, directed by the minister of public health through Capacity Building for Results (CBR) process and approval of the President. NMHRA executive director will be reporting to the minister of public health. The NMHRA will have an executive committee which will be led by the executive director in the areas of implementation of strategies, ensuring merit-based competition, and monitoring the departments. The NMHRA consists of several administrative units based on the proposed duties; every unit is managed by a head accountable to the executive director.

Proposed Structure of NMHRA



6. Legal Status

NMHRA, at first was established by the legislative order of the President, and it has been updated with the approval of medicine and health product law and conformity with certain other laws. Therefore, it will have a permeant legal status.

7. Amendment of Current Structures, Including the GDPA

In the pharmaceutical sector there are two types of activities: regulatory and nonregulatory. The following table elaborates the the regulatory and nonregulatory duties.

Regulatory Duties	Nonregulatory Duties
1. Licensing of premises, practices, and personnel 2. Evaluation and registration of medicines and health products 3. Inspection and enforcement 4. Medicines and health products classifications 5. Quality control and research 6. Regulation and control of medicines information and promotions (advertisement) 7. Pricing and price control 8. Regulation and control of clinical trials 9. Market authorization and lot release 10. Control of narcotic, psychotropic substances and precursors 11. Development of legislative and regulatory documents	1. Developing policies and strategies at the national level 2. Promote rational medicine use 3. Development and updating of Essential Medicine List and Afghan National Formulary 4. Assist in development of standard treatment guidelines 5. Pharmaceutical Information Management System (PMIS) 6. Planning on the medicine needs at the national level 7. Pharmaceutical human resources capacity improvement by coordination with relevant entities 8. Supporting local manufacturing

Currently the abovementioned activities are carried out by different MoPH departments. According to this document, all the regulatory activities from different departments (e.g., GDPA, HLIED, and M&E Directorate) will be brought under one single entity, that is NMHRA. The structure of directorate of quality control laboratories also will be included under NMHRA.

GDPA will be included as the General Directorate of Pharmaceutical Services (GDPS) in the organizational structure of the MoPH, the aim of which will be improvement and development of pharmaceutical services provision in order to ensure access and rational use of medicine and health products, including support to the national pharmaceutical production industry. Fifty current GDPA personnel carry out nonregulatory activities; this will be adjusted under GDPS and GDPS will carry out the nonregulatory activities according to the abovementioned schedule.

NMHRA will be established through amendment of a number of posts in GDPA, HLIED, and incorporation of medicine and food quality control laboratories. In short, the GDPA has 142 technical and nontechnical employees in the regulatory section. The HLIED pharmaceutical sector inspection department has 22 technical and nontechnical staff, and medicine control laboratories has 42 technical and nontechnical staff. The total number of these employees is 206. This entity requires a total of 277 posts and currently 206 posts are available, and 71 additional posts are required. (For further details please refer to table 5.)

After the approval of this document, the first step will be structural changes, where the MoPH, in cooperation with its health partners, will take practical steps in implementing this initiative. It is

proposed that, in order to ensure effective operation of this entity, employees must be recruited up to grade 5 through CBR process.

8. Required Support from Certain Ministries

Financial and political support is among the most vital elements in establishment and successful operation of NMHRA. Therefore, in addition to the president's legislative order, support from the Ministry of Justice (for the acceleration of finalizing the updated medicine and health product law) and support from the Ministry of Finance (to allocate and approve annual budget) will be required.

9. Funding

Funding the NMHRA will be ensured through charging fees for services, budget allocation from the government, and donor assistance. It is also deemed necessary that the Ministry of Finance put the accumulated revenues of this entity at the disposal of this entity. The budget allocations by the government will be vital for the first few years of inception because the accumulated revenues may not be sufficient to cover expenses. In case the revenues from the registration of medicine and health products and license issuance are sufficient to cover the operation expenses, then the government budget allocation can be reduced gradually. The experience of some countries (such as New Zealand, Zimbabwe, and Australia) shows that the revenues obtained in the long run have been sufficient to cover expenses, but in most of the countries reviewed, these expenses are covered by charging fees and government budget. (For further details please refer to table 1.)

Technical assistance will be provided by WHO, USAID, and the World Bank. At the same time, a portion of these expenses included in the proposed budget (such as those incurred for trainings, development of regulatory documents, database creation, medicine quality control laboratory strengthening, strengthening of medicine evaluation, and registration system) have been promised by these organizations by 2017. However, they will not fund the operation expenses, salaries, and expenses incurred on repair of buildings. Notably, 74 percent of the proposed posts are already included in the current organizational structure of the MoPH. (For further information please refer to table 5.)

The required budget for the first year of NMHRA inception will be 2,411,520 USD, out of which 37% will be donor-funded, and 1,520,920 USD will be required from the government budget. The bigger portion of the required budget from the government will cover salaries and operation expenses which are currently being financed by the government, and will be ensured through transfer of personnel from different MoPH departments to NMHRA. The accumulated revenues of the GDPA (around 500,000 USD in a year) and revenues from quality control laboratories (around 180,000 USD in a year) are also being delivered to the government account. The revenues and current budget is 1,230,000 USD and about 290,000 USD is needed for the first year.

For the years after first (2nd and 5th year), on average, 1,594,520 USD will be required (44% less than the needs of first year). In addition to the government budget and charged fees, the NMHRA will be funded with donor financial support. (For further details refer to table 6.) Annual audit will take place on the operations of NMHRA. The fees charged for the registration of medicines is 5000Afs, and for quality control of items the fee is charged according to the expenses; these feeds will be reviewed and inspected in the first phase after the establishment of NMHRA in the country.

Establishment of secondary administrative structures at the provincial level

Currently, at the provincial level across the country, a total of about 135 individuals are employed in the HLIED, which, on average is 4.1 workers per province (minimum number 2 to maximum of 7 employees). With the creation of NMHRA, the process of provincial organizational structure reforms will take place, and will include the employees of these departments too. This reform plan exists in the MoPH plan and will not only rationally arrange this specific department, but also adjust the

provincial organizational structure according to strategic requirements. It's expected that, during this reform, no new employees will be required, and the activities and duties will be rationally assigned.

10. Draft ToR of NMHRA

Duties of NMHRA

Proposed duties for NMHRA are as follows:

- Drafting relevant laws and regulations
- License issuance to establishments and pharmacists
- Inspection and enforcement of relevant medicine and health product laws and regulations
- Registration of medicine and health products
- Quality control, including laboratory analysis (pre-market surveillance)
- Monitoring the quality and safety of medicine and health products supplied to the market (post-market surveillance)
- Regulation and control of promotions and advertisements
- Control and setting the prices (valuation)
- Control of narcotics and psychotropics
- Issuing permit to supply to market from customs
- Regulation and control of clinical studies and investigation

Scope of basic powers and responsibilities of units of NMHRA are as follows:

I. Directorate of Pre-Market Services Integration has the following departments and duties:

1. **Policy and planning** (planning, coordination, communications, information, M&E, and drafting legislative documents)
   This section is responsible for planning and developing policies for NMHRA. Planning, reporting, M&E, ensuring coordination, communications with national and international organizations, exchange of information and compilations, and updating legislative documents in coordination with relevant organizations are the main responsibilities of this section. This section consists of the following departments:

   1) Planning and evaluation
   2) Coordination, communications, and information
   3) Drafting legislative documents

2. **Licensing**
   The Licensing section, in cooperation with technical committees and the Inspection section, will be responsible for issuing license to productions, importations, distribution, and retail sale of medicine and health products in the public and private sector after assessing the standards relevant to the establishments. This section, considering its volume of work and required expertise, will be at least made up of four departments:

   1) Issuing license to manufacturing enterprises following the laws and guidelines on good production practices
   2) Issuing license for the medicine importation companies and distributors following the laws and guidelines on good production practices, distribution, medicine storage, and certain other relevant legislative requirements

3) Issuing license to medical stores following guidelines on good practices of medicine storage, dispensing to the patient, and certain other relevant legislative requirements
4) Issuing license to pharmacy workers in medical stores, distributors, and manufacturing factories

3. Medicine and health product quality control laboratory

The quality control section operates as a source measuring the product quality, and is responsible for testing the medicines and health products in terms of quality so that they are permitted to be supplied to the market, including analysis and control of sample collected from the market. The main aim of the laboratories is to make sure that the better quality products are made accessible to the public. This unit will have the following departments:

1) Quality Assurance Department
2) Investigation and Development Department (testing methods)
3) Department of Physiochemic Test of Medicines
4) Department of Microbiologic Test of Medicines
5) Department of Biologic Test (pharmacologic, toxiocologic, biochemic)
6) Department of Testing Medical Tools and Equipment
7) Department of Testing Traditional Medical Products and Cosmetics
8) Animal, Chemical Standards and Samples Retention Storage Department

4. Permit to market supply and pricing

This section will be responsible for issuing permit for the importation pharmaceutical products according to the annual national required amount, quarantining the products, taking sample from the products arrived at the customs or products at the local industries, sending them to the Quality Control Department, issuing permit to market supply, and setting price for the products. Considering the type of its activities, this unit will at last have the following departments:

1) Department of Market Supply Permit Issuance
2) Pricing Department

5. Medicine and health product evaluation and registration

The medicine and health product evaluation and registration section, with cooperation from relevant technical committees and inspection and quality control sections, will take up the responsibility for technical study and evaluation of medicine and health products quality, effectiveness, and safety before their registration; inspection of place of production; and quality test of the products. This section, according to the type of products and required expertise, will consist of following departments:

1) The Medicine Registration Department, with cooperation of the relevant technical committee, will be responsible for pharmaceutical products evaluation and registration.
2) Health Product Registration Department will be responsible for the evaluation and registration of medical equipment, medical tools, and cosmetics (e.g., shampoo, soaps, and certain other products) according to the definitions of health product law.
3) Biological Products Registration Department will be responsible for the evaluation and registration of biological products used by citizens.
4) Traditional Medical Products Department is responsible for evaluation and registration of supplementary products such as homeopathy products, herbals, Chinese, ayurvedic,

and registration of natural and herbal products and food item supplements according to the legislative documents and regulatory guidelines.

6. **Regulation and control of clinical studies**
   The regulation and control of clinical studies section is responsible for the evaluation and approval of the clinical studies protocols, considering the technical standards of study and monitoring the conformity of operations against good study practices guidelines.

II. Directorate of Post-Market Services Integration has the following departments and duties:

1. **Inspection and enforcement of laws and regulations**
   This section is responsible for review and implementation of disciplinary or punitive orders (in cooperation with relevant entities) on all the public and private establishments that are involved in manufacturing, importation, storage, dispensing, and distribution of medicines and health products. The review and inspections can be carried out before the award of the permit, so that it is ensuredthat the establishments are in compliance with the proposed standards, or the inspection and review can be fulfilled after the award of the permit in order to ensure the implementation of standards or addressing the complaints. This section, considering its load of work and required expertise, will at least have three departments:

   1) Inspection of national and foreign manufacturing company and award of certificate of good production practices for the local producers
   2) Review and inspection of storage and distribution centers of products
   3) Inspection of medical stores, traditional medicine, and certain other health products in the market

   Every department will have one head and several inspection specialists, and all their activities will take place according to the standard procedures and written documents. This section is responsible for coordination and recollection of harmful products from the market, monitoring the safe disposal of medicines and data collection on disposed and eliminated medicines in the country.

2. **Market surveillance (pharmacovigilance)**
   The pharmacovigilance surveillance section, in cooperation with relevant technical committees and the relevant organizations, is responsible for the regular surveillance and collecting of all types of information about safety (especially adverse reactions), quality, and effectiveness of registered products; analysis and scientific study about collected information; and presenting recommendations to the NMHRA according to the findings. This section considering its activities will have the following departments:

   1) Pharmacovigilance information collection and analysis center
   2) Medicine and health products quality complaints collection section

3. **Promotions and advertisements control**
   The promotion and advertisement control section is responsible for the evaluation and confirmation of advertisements and approval of texts of advertisements according to the legislative documents and ethical and technical standards, and making sure that wrong and improper information is not disseminated to prescribers and consumers. This section will have two main duties and responsibilities: evaluation of advertisements, and approval of advertisements.

III. Service Section (finance, admin, human resources, IT)

The services section is responsible for all the support services to NMHRA, including financial and budgetary issues (such as bank accounts), facilitating relevant activities, training programs, logistic and transportation issues, and maintenance. In addition, the technical support and information technology (including NMHRA database) also falls under the responsibilities of this section which will at least have the following departments:

1) Human Resources Department
2) Finance Department
3) Administrative, Archive and Logistic Department
4) IT Department
5) Maintenance Department

Table 3: NMHRA Draft Implementation Plan with Time Frame

	Activities		Responsible	Collaborator	Time frame		Assumption
					1394	1395	
1	**Finalization of NMHRA concept note and plan for establishing**						
	1.1	Appoint an authorized committee to develop NMHRA concept note and plan for establishment of NMHRA	MoPH	Health stakeholders	X		
	1.2	Submit the concept note and plan to HE president for approval	MoPH	--	X		Access
	1.3	Achieve president approval on establishment of NMHRA	MoPH	Presidential Office	X		Stay on / pose
	1.4	Assign Board member and conduct informative meeting to Board members.	MoPH	Related Administrations	X		Resources
2	**Human Resource Recruitment**						
	2.1	Structures draft and codification of individual roles and department responsibilities	Assigned Committee		X		Collaboration
	2.2	Management positions announcement	MoPH	Administrative Reform Commission	X	X	Other Administrations
	2.3	Conduct Board members working group (including suggestion of NMHRA director in one of their meetings)	Board	Presidential Office	X	X	Related Administrations
	2.4	Staff recruit and submit responsibilities	MoPH	Administrative Reform Commission	X	X	
3	**Provide necessary infrastructure and required equipment**						
	3.1	Provide building for NMHRA (1600 square meters office space, including 80 rooms)	MoPH	Ministry of Finance	X	X	
	3.2	Provide the required equipment for NMHRA (for 160 working desks)	MoPH	Ministry of Finance	X	X	
4	**Seek technical support from World Health Organization**						
	4.1	Provide TA for NMHRA to develop the SOPs where is needed	WHO	Health	X	X	

Activities			Responsible	Collaborator	Time frame		Assumption
					1394	1395	
				Stake holders			
	4.2	Provide TA for the NMHRA for the development of appeals mechanism	WHO	Health stake holders	X	X	
	4.3	Provide TA to NMHRA in conducting of self-assessment (using WHO tools)	WHO	Health stake holders	X	X	
	4.4	Sustainable technical support (especially in first two years) to ensure the technical effectiveness	WHO	Health stake holders	X	X	
5	**Develop and finalization of detailed legal and operational documents**						
	5.1	Committee assignment to develop regulation and draft SOPs.	Board	MoPH	X		
	5.2	Development of regulatory and SOPs drafts.	Assigned Committee	Health stake-holders	X	X	
	5.3	Conduct a consultative workshop for consensus on the proposed regulatory and standard operation procedures guideline draft.	MoPH	Health stake-holders		X	
	5.4	Board and other related administrations endorsement on the standard operation procedures guideline draft	Board	MoPH		X	
	5.5	Accelerate the endorsement and approval process of Medicine Law and Pharmaceutical Products.	MoPH	Ministry of Justice	X	X	
6	**Mobilizing the resource and seek Political Support**						
	6.1	Discuss and agree with Ministry of Finance for collection, remittance, and retention of fees accruing through the NMHRA	MoPH	Board- MF	X	X	
	6.2	Provide mechanism for sustainable financing and advocate with government and donors to secure the required budget	MoPH	Health stake holders		X	
	6.3	Public education / awareness on NMHRA functions	MoPH	Health stake holders	X	X	
	6.4	Regulatory affairs challenges, development, and information sharing with related entities.	MoPH	Board	X	X	
	6.5	Foster collaboration with local, regional and international organizations for knowledge and information exchange.	MoPH	Board	X	X	
7	**Improve products Registration and Market Authorization Systems**						

Activities			Responsible	Collaborator	Time frame		Assumption
					1394	1395	
	7.1	Create new Medicine Registration Guideline.	MoPH	Health Stake holders	X	X	
	7.2	Re-registration of Marketed products.	MoPH	Private Sector Associations		X	
	7.3	Registration of new products that requests.	MoPH	--	X	X	
8	**Improve Pharmaceutical establishments licensing Systems**						
	8.1	Develop system for registration of premises and licensing of pharmaceutical establishments and technical staffs (with SOPs) in accordance to new Guidelines	MoPH	MT and AISA(Afghanistan Investment Support Agency)		X	
	8.2	Re-licensing of pharmaceutical Premises	MoPH	Private Sector union		X	
9	**Build institutional and organizational capacity of NMHRA to perform the pre- and post-licensing inspections.**						
	9.1	Establish inspection plan for different related premises	MoPH	Health Stake holders	X	X	
	9.2	Development of inspection Guidelines	MoPH	Health Stake holders	X		
	9.3	Revision of inspection checklists for pharmaceutical establishments	MoPH	Health Stake holders	X	X	
	9.4	Establish inspection database	MoPH	Health Stake holders	X	X	
	9.5	Conduct training courses for effective inspection	MoPH	Health Stake holders		X	
	9.6	Quarterly review of defined indicators for sustainable tracking of the condition	MoPH	Health Stake holders		X	
10	**To ensure quality of supplied medicines in Afghanistan through**						

Activities			Responsible	Collaborator	Time frame		Assumption
					1394	1395	
	enhancing the medicines quality control laboratory (MQCL) services at the tier three testing as defined by the National Medicines QA Policy.						
	10.1	Integrate the Medicine Quality Control Laboratory (MQCL) into NMHRA	MoPH	Health Stake holders		X	
	10.2	Feasibility analyses of finding gaps and opportunities	MoPH	Health Stake holders		X	
	10.3	Committee assignment to review regulatory and standard operation procedures guideline.	Board	Health Stake holders		X	
	10.4	Development of regulatory and Standard Operation Procedures Guideline Draft	Assigned Committee	Board	X		
	10.5	Conduct a consultative workshop for consensus on the proposed legal and Standard Operation Procedures Guideline Draft.	MoPH	Health Stake holders		X	
	10.6	Board and other related entities endorsement on the regulatory and Standard Operation Procedures Guideline.	Board	MoPH		X	
	10.7	Establish capacity building plan	MoPH	Health Stake holders		X	
	10.8	Conduct training courses for staff	MoPH	Health Stake holders			
	10.9	Provide the required office equipment	MoPH	Health Stake holders - MF		X	
	10.10	Upgrade the MQCL to the level that will be certified by the ISO 17025 and to get its certificate.	MoPH	Health Stake holders		X	
	10.11	Feasibility analyses for necessity establishing QCLs at regional level.	MoPH	--		X	
11	**To operationalize a market surveillance system (pharmacovigilance)**						
	11.1	Establish technical Committee for development of Policies, Strategies and Guidelines	Board	Health Stake holders		X	

Activities			Responsible	Collaborator	Time frame		Assumption
					1394	1395	
	11.2	Seek technical support from World Health Organization	MoPH	Health Stake holders		X	
	11.3	Finalization of documents through Board	Board	MoPH		x	
	11.4	Establish information and complaints/ feedback office	MoPH	Board		X	
	11.5	Staff Capacity building	MoPH	Health Stake holders		X	
12	**Improve mechanisms to regulate and control medicines promotion and advertisement.**						
	12.1	Develop a regulatory guideline on control of promotion and advertising	Board	Health Stake holders		X	
	12.2	Conduct informative workshop for Private Sector	MoPH	--		X	
	12.3	Share information /updates on Guideline via posts, Workshops, Meetings and etc. … with all related Entities.	MoPH	Board		X	
	12.4	Collaborate with inspection teams to track the implementation of the Guidelines	MoPH	--		X	
13	**Improve mechanisms to control medicines pricing and determine price**						
	13.1	Develop medicines pricing policy or Guideline.	Board	Health Stake holders		X	
	13.2	Establish a price control mechanism	Board	Health Stake holders		X	
	13.3	Collaborate with inspection teams to track the implementation of the Guidelines	MoPH	--		X	
14	**Strength and control of medicines importation and release permission**						
	14.1	Develop and finalize a Guideline for importation of medicines	Board	Health Stake holders		X	
	14.2	Finalize policy for narcotics, psychotropic and controlled medicines	Board	Health Stake holders		X	
	14.3	Develop and finalize a Guideline for sampling of medicines (chain of Custody) (with SOPs)	Board	Health Stake holders		X	
	14.4	Establish accredit system	Board	Health Stake holders		X	

Activities			Responsible	Collaborator	Time frame		Assumption
					1394	1395	
15	**Staff capacity improvement in technical and management sections**						
	15.1	Evaluate the staff capacity gaps	MoPH	Health Stake holders	X		
	15.2	Establish capacity building plan	MoPH	Health Stake holders	X	X	
	15.3	Conduct training courses in the Country	MoPH	Health Stake holders		X	
	15.4	dispatch limited individual staff for trainings to out of the Country/abroad	MoPH	Health Stake holders		X	
	15.5	Seek technical Administration supports, especially World Health Organization for conducting of trainings	MoPH	Board		X	
	15.6	Evaluate the effectiveness of training courses	MoPH	Health Stake holders		X	
	15.7	Conduct study tours to the countries the same level and similar successful Administrations with Afghanistan.	MoPH	Health Stake holders		X	
16	**Annual survey of the market**		MoPH	Health Stake holders		X	
17	**Annual assessment of NMHRA and development of the next year plan**		MoPH	Health Stake holders		X	

Table 4**:** Monitoring Framework

4.1. Indicators on use of procedures and output sources

No	Indicator	Definition (Numerator and Denominator)	Information source	Approving source	Planned number	Annual Target
1	Employee recruitment	Number of employees recruited/ total number of planned employees	The entity reports	Daily attendance sheet	278people	More than 90%
2	Drafted rules and regulations	Number of rules & regulations drafted/ total number of planned rules & regulations to be drafted	The entity reports	Copy of rules & regulations	2	%100
3	Development of operative procedures	Number of operation procedures developed/ total number of planned operation procedures	The entity reports	Copy of operative procedures	10	%100
4	Managerial and technical staff capacity evaluation	Number of personnel evaluated for training needs/ total number of current personnel	The entity reports	Capacity evaluation document	1	%100
5	Managerial and technical staff training	Number of personnel trained at least once in a year/ total number of current personnel	The entity reports	Training programmes report	Will be specified	%100
6	Monitoring findings Analysis of monitoring findings	Number of analysis carried out/ number of analysis planned	The entity reports	Copy of analytic reports	4	%100
7	Medicine price control mechanism establishment	Medicine price control mechanism establishment	The entity reports	Copy of documents	1	%100
8	Creation of a system issuing accredition to pharmaceutical establishments	Number of guidelines developed/ number of guidelines planned	The entity reports	Copy of checklists & guidelines	Will be specified	%100
9	Effectiveness evaluation of training programs	Number of training programs being evaluated for effectiveness/ total number of planned training programs	The entity reports	Copy of effectiveness evaluation report	Will be specified	%100
10	Updating the EML/LML	Number of updated lists/ number of planned lists	The entity reports	Copy of updated lists	2	%100

4.2: Coverage and effectiveness indicators

No	Indicator	Definition (numerator and denominator)	Information sources	Approving sources	Baseline		Annual target
					Date	No	
1	% of drugstore inspected in Kabul	Number of medical stores inspected at least once in a quarter/ Nnumer of registered medical stores in Kabul	Quarterly Report	Checklist copy	Qaws 94	0	More than 90 % (2653 medical stores)
2	% of manufacturing company inspected in Kabul	Number of manufacturing companies inspected at least once in a quarter/ Nnumer of manufacturing companiesin Kabul	Quarterly Report	Checklist copy	Qaws 94	0	%100
3	% of medicine storages inspected in Kabul	Number of medicine storages inspected at least once in a quarter/ Nnumer of medicine storages in Kabul	Quarterly Report	Checklist copy	Qaws 94	0	More than 90 %
4	% of drugstore inspected in provinces	Number of medical stores inspected once in a quarter/ numer of registered medical stores in provinces	Quarterly Report	Checklist copy	Qaws 94	0	More than 50%
5	% of manufacturing companies inspected in provinces	Number of manufacturing companies inspected once in a quarter/ numer of medicine storages in provinces	Quarterly Report	Checklist copy	Qaws 94	0	More than 90 %
6	% of medicine storages inspected in provinces	Number of medicines storages inspected once in quarter/ numer of medicine storages in provinces	Quarterly Report	Checklist copy	Qaws 94	0	More than 70%
7	% of redressed complaints on quality of medicines	Number of complaints arrived/ number of complaints recieved	Quarterly Report	Complaints follow up report	Will be specified	Will be specified	%100
8	% of counterfeit medicines in market	Number of counterfeit medicine found in market/ total number of surveyed items	Yearly survey	Survey report copy	Will be specified	Will be specified	70 % less than the percentage received
9	% of illegal medicines in the market	Number of illegal items in the market / total number of surveyed items	Yearly survey	Survey report copy	Will be specified	Will be specified	70 % less than the percentage received
10	% of tests of medicines quality processed in a suitable time	Number of tests carried out on time specified by the guideline/ total number of requested tests	Quarterly Report	Registeration	Will be specified	Will be specified	More than 90 %
11	% of manufacturing company license which has been processed in a	Number of licenses issued according to the specified time in the guideline/ total number of requested licenses	Quarterly Report	Registeration	Will be specified	Will be specified	More than 90 %

	suitable time						
12	% of importation companies license which has been processed in a suitable time	Number of licenses issued according to the specified time in the guideline/ total number of requested licenses	Quarterly Report	Registeration	Will be specified	Will be specified	More than 90 %
13	% of importation companies which has been adjusted to the updated standards	Number of companies in conformity with the new standards/ total number of registered companies	Quarterly Report	Copy of company's evaluation report	Qaws 94	0	238 companies (100% active)

Table 5: NMHRA Staff Scales Description and Distribution status in Departments

NMHRA's staff distributing chart (negative sign indicated vacant position)					
S/N	**Departments**		**No. of purposed staff**	**No. of exist staff**	**No. of extra required staff**
1	NMHRA Executive Director and lawyer Advisor				
		Office responsible of NMHRA	1	0	0
		Lawyer Advisor	1	0	-1
2	Medicine Inspection and Registration Department		1	1	0
		1)Medicine Registration Department	5	5	0
		2)Medical devices Registration Department	5	5	-1
		3) Biological products Registration Department	3	0	-3
		4) Traditional products Registration Department	3	2	-1
3	Establishment Licensing Departments		1	1	0
		1) Manufacturers Licensing Department	3	2	-1
		2) Importers licensing Department	4	2	-2
		3) Distributers Licensing Department	3	3	0
		4) Pharmacy Licensing Departments	4	8	4
4	Inspection and law enforcement Department		1	1	0
		1)Inspection of internal and external Manufactures	3	1	-2
		2) Inspection of distributed and Imported products	8	2	-6
		3) Inspection of Retail pharmacies and Traditional Medicines in Kabul (one supervisor for 50-60 outlets)	60	21	-39
		4) Inspection of Retail pharmacies and Traditional Medicines in Provinces (related to PPHDs)	0	0	0
5		Medicines and Medical Devices Quality Control Department	1	1	0
		1) Quality Control Department	2	0	-2
		2) Analyses method and Development Department	3	0	-3
		3) Medicines Physico- Chimic testing Department	20	18	-2
		4) Medicines MicroBiologic testing Department	5	0	-5
		5) Biologic testing Department (Pharmacology, Toxicology and Bio chemic)	5	0	-5
		6) Medical Devices testing Department	7	0	-7
		7) Traditional and cosmetics products experiment Department.	5	0	-5
		8) Animal care unit, samples, chemicals and standards	2	3	1

6	Market surveillance unit(pharmacovigilance)		1	0	-1
		1)collection and pharmacovigilance analysis center	3	2	-1
		2) medicinal quality and health products complaint collection unit	2	0	-2
7	License allowance to market and Appraisal unit		1	1	0
		1)Medicine and health products license allowance Department(proforma registration, Sampling, Quarantine including narcotic drugs)	12	28	16
		3) pricing determination department	3	3	0
8	Advertising and publicity control department		1	0	-1
		1)assessment and approval of Advertising and publicity department	3	0	-3
9	Regulated and controlled (trials) clinical studies unit		1	0	-1
		Regulated and controlled (trials) clinical studies Department	2	0	-2
10	Support unit(Planning, coordination, communications, Monitoring and evaluation, Approval of legislative documents)		1	1	0
		1)planning and evaluation department	4	1	-3
		2) coordination, communication, and information department	3	3	0
		3) Approval of legislative documents department	3	3	0
11	Service unit(financial and administrative, human resources and information technology)		1	0	-1
		1)human resources department	65	77	12
		2) financial department	4	3	-1
		3) Administrative, Archive, logistics and service department	4	3	-1
		4) information technology department	4	0	-4
		5) save & Care unit	3	4	1
Total			277	206	-71

Table 6: Required Budget Description for NMHRA (Currency: US$)

Description		Proposed Position	Unit cost in USD	Unit	Number	Duration (month)	1st Year	2nd Year	3rd Year	4th Year	5th year	Reference donor
1.Management cost												
1.1.	**Salaries & Benefits**											
	Cehif Excuetive Director of NMHRA Salary	1	4000	Person	1	12	48000	48000	48000	48000	48000	Govrnment
	Head of NMHRs 3deps/directorats and Lawyar Advisor Salaries	2	2000	Person	4	12	96000	96000	96000	96000	96000	Govrnment
	Head of of 9 Departments salaries	3	850	Person	9	12	91800	91800	91800	91800	91800	Govrnment
	Technical Officers salaries (Advertsing and Promotion Controlling Depart)	4	450	Person	3	12	16200	16200	16200	16200	16200	Govrnment
	Technical officers salaries (Expets for QC lab Depart)	4	450	Person	20	12	108000	108000	108000	108000	108000	Govrnment
	Technical officers salaries (analysts for QC lab Depart)	4	450	Person	27	12	145800	145800	145800	145800	145800	Govrnment
	Technical officers salaries (inspection & law enforcement Depart)	4	450	Person	71	12	383400	383400	383400	383400	383400	Govrnment
	Technical officers salaries (pharmaceutical establishment licensing Depart)	4	500	Person	14	12	84000	84000	84000	84000	84000	Govrnment
	Technical officers salaries (product evaluation and registration Depart)	4	500	Person	17	12	102000	102000	102000	102000	102000	Govrnment
	Technical officers salaries (Market Survellance and Products tracking or pharmacovigilance Depart)	4	500	Person	5	12	30000	30000	30000	30000	30000	Govrnment
	Technical officers salaries (market authorization, pricing and release permission Depart)	4	500	Person	15	12	90000	90000	90000	90000	90000	Govrnment
	Technical officers salaries (clinical trials control and Regulating Depart)	4	500	Person	2	12	12000	12000	12000	12000	12000	Govrnment
	Suportive Officers salaries Planing, Coordinating , Liasing and Drafting of legal documents Depart)	0	300	Person	10	12	36000	36000	36000	36000	36000	Govrnment
	Service staff salaries (Admin/Finance/HR/IT officers)	0	300	Person	10	12	36000	36000	36000	36000	36000	Govrnment

	Description	Proposed Position	Unit cost in USD	Unit	Number	Duration (month)	1st Year	2nd Year	3rd Year	4th Year	5th year	Reference donor
	Other support staff(including cleaner, guards, drivers)	0	200	Person	69	12	165600	165600	165600	165600	165600	Govrnment
	Subtotal Salaries & Benefits due 90% of positions are filled				**277**		**1,300,320**	**1,300,320**	**1,300,320**	**1,300,320**	**1,300,320**	
1.2.	**Goods & Services:**											
	Travel & transport						**102,000**	**102,000**	**102,000**	**102,000**	**102,000**	
	Staff per diem		10	Person	100	12	12,000	12,000	12,000	12,000	12,000	Govrnment
	Staff local transportation cost		1,500	Unit	4	12	72,000	72,000	72,000	72,000	72,000	Govrnment
	Local airfare		150	Person	10	12	18000	18000	18000	18000	18000	Govrnment
	Communications						**21,600**	**21,600**	**21,600**	**21,600**	**21,600**	**5%**
	Telephone & top up cards		50	Person	20	12	12,000	12,000	12,000	12,000	12,000	Govrnment
	Internet install & monthly fees		800			12	9,600	9,600	9,600	9,600	9,600	Donor
	Repairs & maint						**12,000**	**12,000**	**12,000**	**12,000**	**12,000**	
	Repair,Maintenance & Spared parts of Vehicle		50		10	12	6,000	6,000	6,000	6,000	6,000	Govrnment
	Repair & Maintenance of Building		500			12	6,000	6,000	6,000	6,000	6,000	Govrnment
	Repair,Maintenance & Spared parts of other equipment & furniture					12						
	Utilities (Facilities)						**18,000**	**18,000**	**18,000**	**18,000**	**18,000**	
	Electricity, water, gas, etc.		1500			12	18,000	18,000	18,000	18,000	18,000	Govrnment
	Fuel						**42,000**	**42,000**	**42,000**	**42,000**	**42,000**	**42,000**
	Vehicle fuel		200	Unit	10	12	24,000	24,000	24,000	24,000	24,000	Govrnment
	Winter heating		100	Room	60	3	18,000	18,000	18,000	18,000	18,000	Govrnment
	Materials & supplies						**196,600**	**23,600**	**23,600**	**23,600**	**23,600**	
	Office supplies (stationeries)		500			12	6,000	6,000	6,000	6,000	6,000	Govrnment
	Printing of documents		7000			4	28,000	5,000	5,000	5,000	5,000	Govrnment
	Hygiene supplies & other consumables		50			12	600	600	600	600	600	Govrnment
	Running cost of equipments (cartidges, tuner etc…)		1000			12	12,000	12,000	12,000	12,000	12,000	Donor
	Purchase Vehicles (5 vehicles)		30,000	Vehicle	5		150,000					Donor
	Development of required documents cost						**15,000**	**15,000**	**15,000**	**15,000**	**15,000**	

Description		Proposed Position	Unit cost in USD	Unit	Number	Duration (month)	1st Year	2nd Year	3rd Year	4th Year	5th year	Reference donor
	Development of the required documents (including regulations, policies, regulatory guidelines, SOPs, etc.		15,000				15,000	3,000	3,000	3,000	3,000	Donor
	Other cost						**60,000**	**60,000**	**60,000**	**60,000**	**60,000**	
	Staff rrecruitment cost									-	-	Govrnment
	Market Survey		50,000	1	1		50,000		50,000		50,000	Donor
	Other cost(Board)		10,000				10,000	10,000	10,000	10,000	10,000	Donor
	Subtotal of Goods & Services						**467,200**	**244,200**	**294,200**	**244,200**	**294,200**	
Total Administrative cost							**1,767,520**	**1,544,520**	**1,594,520**	**1,544,520**	**1,594,520**	
2. Training cost												
2.1.	Medicines inspectors - initial & refresher training (including all costs)		5000		2		10,000	-	-	10,000	-	Donor
2.2.	QC lab staff - initial & refresher training (including all costs)		10,000		2		20,000	-	-	10,000	-	Donor
2.3.	Product dossier assessors - initial & refresher training (including all costs)		7,000		2		8,000	-	-	-	-	Donor
2.4.	Pharmacovigilance staff - initial & refresher training (including all costs)		10,000		1		10,000	-	-	-	-	Donor
2.5.	Clinical trials technical staff - initial & refresher training (including all costs)		8000		1		8,000	-	-	-	-	Donor
2.6.	Medicines advertisement staff - initial & refresher training (including all costs)		8,000		1		8,000	-	-	-	-	Donor
2.7.	Sponsor a core set of professionals for various postgrduate courses		15,000	Person	4		60,000	-	-	-	-	Donor
2.8.	Upgrading of QC lab		500,000		1		500,000	-	-	-	-	Donor
Total Training costs							**624,000**			**20,000**		
3. Building												

Description		Proposed Position	Unit cost in USD	Unit	Number	Duration (month)	1st Year	2nd Year	3rd Year	4th Year	5th year	Reference donor
and equipment for NMHRA												
3.1.	Building for NMHRA			1	1							
3.2.	Office equipment for NMHRA		20,000	1	1		20,000	5,000	5,000	5,000	5,000	Donor
Total costs							**20,000**	**20,000**	**20,000**	**20,000**	**20,000**	
GRAND TOTAL							**2,411,520**	**1,564,520**	**1,614,520**	**1,584,520**	**1,614,520**	**8,789,600**

Glossary

Inspection: Inspections are part of the overall drug quality assurance system. The objective of inspecting pharmaceutical manufacturing facilities is either to enforce Good Manufacturing Practice (GMP) compliance or to provide authorization for the manufacture of specific pharmaceutical products, usually in relation to an application for marketing authorization. A further aspect of pharmaceutical inspection is monitoring the quality of pharmaceutical products in distribution channels, from the point of manufacture to delivery to the recipient, as a means of eliminating the hazard posed by the infiltration of counterfeit drugs.

Efficacy: The ability of a medicine, whether a modern medicine or traditional, to treat or control disease.

License: An official document issued by the competent medicines regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy, and quality.

Pharmacovigilance: the science of detection, assessment, and prevention of adverse reactions and related problems, as a major resource for ensuring the safe and rational use of medicines.

Quality: Compatibility of a product with related standards that is previously determined.

Registration of medicine: The process of registering medicines to be allowed to be sold on the market, which includes evaluation of safety, efficacy, and quality of the pharmaceutical product.

Procurement: All management activities required for providing sufficient health products of assured quality, procured at the lowest price, and in accordance with national and international laws to the end user, in a reliable and timely fashion.

Rational Medicine Use: Patients reciece medicines appropriate for their clinical needs in doses that meet their individual requirements for an adequate period of time, and at the lowest cost of them and their community.

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