Ministry of Public Health
General Directorate of Pharmaceutical Affairs
Avicenna Pharmaceutical Institute

Afghanistan National Medicines Policy

2014–2019

CONTENTS

PREFACE

This National Medicines Policy (NMP) is the overall policy document for the Afghanistan pharmaceutical sector. It constitutes part of the continuous efforts by the Ministry of Public Health (MoPH) and its stakeholders to ensure the availability, accessibility, affordability, and rational use of safe, efficacious, and quality medicines. The NMP aims to guide the provision of comprehensive pharmaceutical services as a major component of health promotion as well as preventive, curative, rehabilitative, and palliative care. It also represents a commitment to building a responsive, sustainable, and viable pharmaceutical industry.

The policy comprehensively covers medicines regulation, quality assurance, selection, supply, and rational use. It reviews mechanisms to secure sustainable financing, build local human capacity for services, and manufacture essential and complementary medicines. Strategies for international cooperation and systems for monitoring and evaluating are also described.

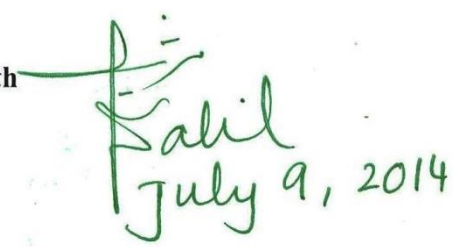
This edition of the NMP was developed through a systematic process, as internationally established. A NMP Task Force (NMPTF) comprised of key technical stakeholders was established under the direct supervision and leadership of MoPH. The NMPTF consulted widely and reviewed the current pharmaceutical situation in Afghanistan. An initial draft policy document was developed and subjected to widespread consultation with stakeholders, both internally and externally. The final draft document was compiled and presented to MoPH, which took the final decision on all aspects of the policy and approved it for implementation.

This policy document will be complemented by a National Pharmaceutical Master Plan (NPMP), which will set out strategies, objectives, activities, and expected outcomes/outputs to implement all components of the NMP.

I am very optimistic that all stakeholders involved in the development of this policy will remain committed to it and will support the Government's efforts to fully implement it. It is also my hope that our development partners will find the policy to be a useful guide in providing technical and financial assistance in the pharmaceutical sector. Hopefully, in the next few years, when we have implemented this policy, we can together rejoice over the positive results of our combined efforts.

I wish to sincerely commend the Strengthening Pharmaceutical Systems (SPS) Project funded by the United States Agency for International Development (USAID) and implemented by Management Sciences for Health (MSH) for the tremendous technical support. I also thank the NMP Task Force members and all those who contributed to the development of this policy document.

Dr. Suraya Dalil
Minister of Public Health



ACKNOWLEDGMENTS

This second edition of NMP has drawn from and been developed based on the contents of the previous policy, while also being informed by changes and developments in the pharmaceutical sector. It was drafted using a systematic process that allowed for extensive consultation by all concerned and involved stakeholders.

The development of this policy began during Dr. Sohaila Seddiq's tenure as Minister of Public Health. Formulating the NMP has involved many staff members of MoPH at both central and provincial levels. Many Afghans, international stakeholders, and donors as well as Stephanie Simmonds, a United Kingdom Department for International Development-supported consultant, contributed to the policy's development and will play a key role in its implementation. We extend our sincere thanks to all.

Also, sincere thanks are given for the contributions of the NMPTF, staff members of MoPH, Ministry of Higher Education, Ministry of Justice, Ministry of Economics, the General Directorate for Pharmaceutical Affairs (GDPA), and national and international organizations, including the World Health Organization (WHO), USAID, SPS, and other donors, which were involved in the revision of the NMP 2014-2019 and will play key roles in its implementation.

The GDPA further expresses its gratitude to the SPS Project for its technical support, and for the financial assistance of USAID.

Pharmacist Abdul Hafiz Quraishi

Jul. 09. 2014

General Director of Pharmaceutical Affairs

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The organizations that contributed to the review process include:

- Ministry of Public Health
    - General Directorate of Pharmaceutical Affairs
    - General Directorate of Administrative and Finance Affairs
    - General Directorate of Health Services
    - General Directorate of Policy and Planning
    - Directorate of Monitoring and Evaluation
    - Legislation Implementation and Ensuring Directorate
    - National Medicines and Food Quality Control Laboratory
- Ministry of Counter Narcotics
- Ministry of Justice
- Ministry of Economy
- Ministry of Higher Education
    - Kabul Medical University
    - University of Kabul, Faculty of Pharmacy
    - Academic Affairs Coordination Directorate
- Afghan National Standards Authority
- Professional associations

  - Pharmacy Association
  - Afghanistan Doctors and Medical Workers Association
  - Afghanistan National Medicines Services Organization

- United Nations organizations

  - World Health Organization
  - UNICEF
  - UNFPA

- Donor representatives

  - USAID
  - European Commission
  - World Bank

- Nongovernmental organization representatives

  - Ministry of Economy, Nongovernmental Organization Department

- Management Sciences for Health

  - SPS
  - Tech–Serve
  - TB CARE I
  - BASICS

- Health Partners International of Canada

Other colleagues and partners who cooperated in development of this policy as technical consultants and oversight bodies:

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ACRONYMS

AMR	antimicrobial resistance
BPHS	Basic Package of Health Services
EML	essential medicines list
EPHS	Essential Package of Hospital Services
FDA	Food and Drug Administration
GDP	Good Dispensing Practice
GDPA	General Directorate for Pharmaceutical Affairs
Global Fund	Global Fund to Fight Aids, Tuberculosis and Malaria
GMP	Good Manufacturing Practice
HRD	human resource development
INN	international nonproprietary name
LML	licensed medicines list
M&E	monitoring and evaluation
MoPH	Ministry of Public Health
MRA	medicines regulatory authority
MSH	Management Sciences for Health
MTC	Medicines and Therapeutics Committee
NGO	nongovernmental organization
NMFB	National Medicines and Food Board
NMP	National Medicines Policy
NMPTF	National Medicines Policy Task Force
NPMP	National Pharmaceutical Master Plan
NQCL	National Quality Control Laboratory
NSTG	National Standard Treatment Guidelines
QA	quality assurance
R&D	research and development
RMU	rational medicine use
SPS	Strengthening Pharmaceutical Systems
SRA	stringent regulatory authority
STG	standard treatment guideline
TORs	terms of reference
TRIPS	Trade-Related Aspects of Intellectual Property Rights
USAID	US Agency for International Development
USD	United States dollar
WHO	World Health Organization
WTO	World Trade Organization

1. INTRODUCTION

Afghanistan National Health System

According to the National Health Policy and Strategy, Afghanistan is a post-conflict country that is in the process of determining its political system. The national health policy was developed based on the expressed core values of the Ministry of Public Health (MoPH), which reinforces the strong perception of MoPH as an institution working for reform. The Government's Public Investment Program 2004 highlighted the need for "accelerated implementation through concerted and focused action" (NHS 2005).

To safeguard the public and ensure the quality of clinical services, in particular, MoPH has been focusing on reviewing, developing, and enforcing relevant legal and regulatory instruments and policies that govern health and health-related work.

The vision of MoPH is: "Better health for all Afghans in order to contribute to economic and social development." The mission statement further articulates a commitment to ensuring the accelerated implementation of quality health care. MoPH aims to achieve equitable, affordable, and sustainable quality support services, including those for pharmaceuticals. The provision of appropriate essential medicines at each level of the public health system is one of the seven core elements of the Basic Package of Health Services (BPHS) for Afghanistan.

National Medicines and Food Board

The National Medicines and Food Board (NMFB) is intended to serve as an advisory body for the implementation of policy and monitoring the general activities of the national medicines regulatory body in relation to medicines and related products.

National Medicines Regulatory Authority

The General Directorate of Pharmaceutical Affairs (GDPA) is the only pharmaceutical regulatory body in the country. To provide better coordination and enforcement of the provisions of the National Medicines Policy (NMP), the GDPA will be promoted to an autonomous medicines regulatory authority (MRA) and will be accountable to the NMFB, and ultimately to the Minister of Public Health. Furthermore, when the independent Food and Drug Administration (FDA) is formed and empowered (according to the National Health and Nutritional Policy 2012-2020; IRA MPH 2005) through legislation and regulation and when the food product regulations become operational, then the MRA will become a part of the FDA.

Until such time, the GDPA will continue to provide the functions of the national MRA.

Vision of the GDPA: The country's needs in terms of pharmaceutical and health products and standard pharmaceutical services are met.

The GDPA mission is: to lead, initiate, and manage all programs and systems relevant to pharmaceuticals and to ensure that all pharmaceutical needs at the country level are met.

The values of the national MRA are:

- Dedication to the country and national interests
- Equity and equality
- Honesty and competence
- Ensure and maintain quality and transparency
- Equal access to quality medicines
- Availability of affordable medicines for the majority of the population
- Observance of professional standards

The working principles of the national MRA are to have—

- Respect, honesty, responsibility, transparency, and accountability for the national benefit
- Evidence-based and with no conflict of interest in decision making for the national benefit
- Effective and efficient equitable pharmaceutical services
- Respect and equitability when dealing with people and all stakeholders
- Quality, effective, safe, and affordable medicines to provide to the majority of the population
- Continuous efforts to improve the pharmaceutical sector so as to more effectively support the national health sector

Afghanistan Pharmaceutical Market

The world pharmaceutical market has been changing dramatically. There has been a significant increase in low-cost, generic pharmaceutical manufacturing in Asia. In contrast to the 1990s, the origin of medicines in use in most developing countries today is now far more likely to be from the Asia region. For Afghanistan, the primary origins of medicines are China, India, Iran, and Pakistan. None of these countries is considered to have stringent regulatory (medicines) authorities (SRA).

In essence, any medicine from a SRA country can be automatically considered to have been adequately quality controlled to internationally accepted standards. Medicines from non-SRA countries are not automatically qualified, but companies from non-SRA countries can still receive individual medicine approval from the World Health Organization (WHO) prequalification, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), and the US Food and Drug Administration provisional registration schemes. However, for a recipient country to ensure an adequately quality assured medicine, a detailed knowledge of the schemes and the individual approvals are required. The Global Fund and numerous other donors require all medicines they fund to be procured from either a SRA country and/or to have received an individual certification from one of the recognized prequalification or registration schemes.

The upshot of this situation is that it is now more difficult to control the quality of imported medicines, and greater regulatory oversight is necessary.

There has been a worldwide increase in the counterfeiting of medicines. WHO estimates that some 10% of medicines on the world market are counterfeit and that in developing countries, the percentage of counterfeit medicines is 25%.

In the current world pharmaceutical situation, there is clearly a need for a strengthened policy and regulatory environment to help protect against counterfeit medicines.

Currently, the total Afghanistan public sector and per capita expenditure for the pharmaceutical sector are not reliably known. The same is true for the total value of domestic pharmaceutical production and imports and exports of active pharmaceutical ingredients and finished pharmaceutical products. This is because of the lack of a database or credible source for collecting this information.

However, in an official report, the GDPA estimates that annually, the private-for-profit and private not-for-profit nongovernmental organization (NGO) sectors hold medicines worth a total of about 111 million dollars (USD). Other sources estimate that the private-for-profit sector accounts for between 70% and 80% of total pharmaceutical consumption and that the annual market may be worth up to double that.

MoPH Commitment to Strengthening the Pharmaceutical Sector

MoPH is responsible for ensuring that medicines distributed in the country are safe, effective, and of standard quality. This responsibility is in accordance with the concept of pharmaceutical management support defined in the Afghanistan National Development Strategy. For some time now, MoPH has demonstrated a strong commitment to strengthening the pharmaceutical sector. For example, the Ministry has continuously supported pharmaceutical and laboratory services despite MoPH's budgetary challenges. The recent Health and Nutritional Policy 2012-2020 (IRA MPH 2005) specifically mentions enhancing the capacity for regulating the pharmaceutical sector through different mechanisms of quality assurance. Furthermore, various task forces, including the National Medicines Policy Task Force (NMPTF), were established at the national level to lead the development of appropriate strategies for medicines quality assurance (QA) for the country.

As stated in the National Health Policy and Strategy, the increasingly pro-active leadership of MoPH has resulted in its being widely considered one of the most progressive and reform-minded of the Afghan ministries. It has acquired the trust of other Afghan Ministries, international donors, multilateral agencies, and NGOs. MoPH is committed to establishing and using standard international level procurement, stocking, and logistics systems to enable international contracting, bidding, and stocking.

To this end, MoPH recently re-launched the National Medicines and Food Board (NMFB) to serve in an advisory capacity to implement the NMP and monitor the national MRA.

To ensure the effective implementation of the national medicines regulatory activities in the country, MoPH will empower the GDPA to form an autonomous, competent, and authorized MRA accountable to the NMFB and, ultimately, to the Minister of Public Health, through appropriate legislation and regulation. And, MoPH will be committed to further improve the MRA as a part of an autonomous FDA (IRA MPH 2010).

Afghanistan NMP 2014-2019

The 2003 Afghanistan NMP document represented a major achievement in establishing basic policies at that time. Since that date, pharmaceutical sector activities in the country have expanded, and the policy is no longer considered adequate for the new challenges and opportunities, both locally and internationally.

The NMP represents a commitment to a goal and a guide for action. The policy expresses and prioritizes the short-, medium-, and long-term goals set by the Government for the pharmaceutical sector and identifies the main strategies for attaining them. It provides a framework within which the activities of the pharmaceutical sector can be coordinated. It covers both the public and private sectors, and involves all the main stakeholders in the pharmaceutical sector.

A well-prepared NMP, presented and printed as an official government statement, is important because it acts as a formal record of aims, decisions, expected outcomes, and commitments. Without a formal policy document, there may be no general overview of what is needed. As a result, some government measures may conflict with others because the various goals and responsibilities are not clearly defined and understood.

This policy document was developed through a systematic process of consultation with all major stakeholders in both the public and private pharmaceutical sectors. The groups involved defined and agreed on the goal and objectives, set priorities, developed strategies, and defined commitments based on available and anticipated resources.

A revised NMP was needed to:

- Present a formal record of values, aspirations, aims, decisions, and government commitments
- Clearly define the national goals, objectives, and set priorities for the pharmaceutical sector
- Identify the strategies needed to meet those objectives and actors responsible for implementing the main components of the policy
- Create a forum for national discussion on these issues

The hope is that this NMP will:

- Contribute meaningfully to the overall national health policy and the provision of health care in the country
- Promote equitable access and availability of quality-assured and affordable medicines used rationally and cost effectively, with correct information on their usage
- Facilitate the availability of quality pharmaceutical services through the development of the pharmacy profession and pharmaceutical activities
- Facilitate the development of a national pharmaceutical industry by providing a clear and stable policy environment
- Facilitate the provision of both governmental and donor funding for medicines

2. GOAL AND OBJECTIVES

Goal

The goals of this new edition of the NMP are to ensure the continuous development of the pharmaceutical sector and to meet the health care pharmaceutical requirements of all people living in Afghanistan, through the provision and use of safe, efficacious, high quality, cost-effective, and affordable medicines and related products. This policy also serves as the guiding document for legislative reforms, service standardization, resource mobilization, and management for improved quality in the sector. This policy will be in line with MoPH's current strategic plan (IRA MPH 2011).

Objectives

The main objectives of NMP 2014 are:

- To ensure the availability and accessibility of safe, efficacious, cost-effective, good quality, and affordable medicines to the entire population of the country.
- Promote good governance of the pharmaceutical sector, in accordance with accepted ethical and professional standards at all levels.
- Strengthen the quality assurance system to guarantee the safety and efficacy of medicines supplied to clients in both the public and private sectors.
- Promote local capacity for the production of essential and complementary medicines.
- Secure sustainable financing and supply of essential and complementary medicines through improved and appropriately documented processes of selection, forecasting, procurement, storage, inventory management, and distribution at all levels of the health care system.
- Promote rational medicines use in the public and private sectors by improving medicines information and prescribing and continuous training and research activities.
- Design systems to make safe, efficacious, high quality, and cost-effective essential, complementary, and traditional medicines available and accessible for rational use in both the public and private sectors.
- Strengthen financing mechanisms to improve sustainability and prudent financial management in the supply of medicines.
- Improve the quantity and quality of human resources for improved pharmaceutical services at all levels of the health system.
- Promote international cooperation and technical assistance for mutual benefit.

3. KEY PRINCIPLES

The NMP is guided by the following principles:

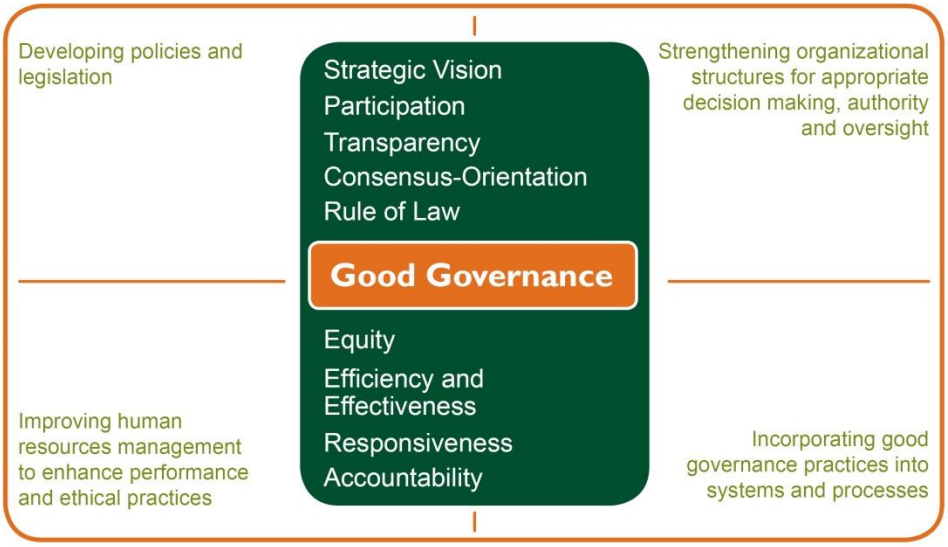
- It is the responsibility of the Government of Afghanistan to ensure equitable access to and rational use of safe, efficacious, high quality, and affordable essential and complementary medicines to all people in Afghanistan, under a sustainable financing system.

- Pharmaceutical services form an essential, critical, and integral part of the national health services system.

- There is a need to develop a client-centered pharmaceutical service that recognizes clients' rights, particularly the right to required information, thereby enabling clients to make informed decisions.

4. GOOD GOVERNANCE

The Government of Afghanistan is committed to the principle of good governance as defined by international conventions and national legislation, and is determined to implement governance that is effective, equitable, participatory, accountable, transparent, responsive, and inclusive and that follows the rule of law.



Adapted from UNDP. 1997. Governance for sustainable human development. http://mirror.undp.org/magnet/policy/

This NMP seeks to ensure that all the principles of good governance relating to the health sector, as defined in detail by the WHO Good Governance of Medicines Program (http://www.who.int/medicines/areas/policy/goodgovernance/en/), are established and implemented throughout the pharmaceutical sector in Afghanistan.

In particular:

Extensive research and coordination has been conducted to ensure that this policy follows the existing laws and legislation and their use in Afghanistan.

Furthermore, the NMP enshrines the Good Governance of Medicines Program's principles of:

- Equitability, from access to essential medicines through affordability of medicines, and applies to all sectors of the pharmaceutical operation in Afghanistan.

- Participation, by promoting the active engagement of all players—public, private, NGOs, donors, United Nations agencies, and partners in pharmaceutical activities.

- Accountability and transparency, through clearly defined responsibilities and open procedures and systems.

- It seeks to be responsive and inclusive by defining a role for the patients and customers, and formalizing complaint procedures and appeals.

5. REGULATION AND QUALITY ASSURANCE

Introduction

Various assessments of Afghanistan's pharmaceutical sector show that there is little capacity for existing medicines regulation and control for both the public and private sectors. Structures, procedures, and policies to regulate the pharmaceutical sector adequately are lacking, including provisions for QA.

A MRA with sufficient capacity and appropriate medicines information is required to ensure the safety, efficacy, and quality of medicines. All MRA functions should work in concert to provide effective public health protection. Legal structures are the foundation of a medicines regulation system.

Since pharmaceuticals are frequently very expensive, they are prone to the production of substandard/spurious/falsely-labeled/falsified/counterfeit medical products .The establishment of viable and sustainable market vigilance through regulatory processes is therefore essential. These processes should be capable of detecting unacceptable products to help provide a deterrent to unscrupulous manufacturers and suppliers.

Objective

To strengthen regulatory and distribution systems to ensure the safety, efficacy, availability, accessibility, and affordability of high quality essential and complementary medicines for all people in Afghanistan

5.1. Regulation

5.1.1. The Government of Afghanistan will remain committed to improving the capacity of medicines regulation to ensure information, availability, safety, efficacy, and quality of medicines in the country.

5.1.2. The Government will further empower the existing NMFB to act as the prime policy making body for all medicines matters and the initial monitoring and appealing body for the MRA.

5.1.3. The Government will restructure the GDPA according to the WHO recommendations to be a fully functional and duly authorized body, and through appropriate legislation, to act as the national MRA.

5.1.4. The Government will provide the necessary resources to strengthen and maintain the capacity of the national MRA.

5.1.5. The Government will provide special incentives to encourage health care providers in the public and private sectors to provide services in remote areas to ensure equitable distribution of pharmaceutical services.

5.1.6. The MRA will:

5.1.6.1. Be an autonomous statutory body accountable to the NMFB and ultimately to the Minister of Public Health.

5.1.6.2. Be responsible for the assessment of and approval for marketing of all medicines for human use.

5.1.6.3. Set up multidisciplinary expert committees that will be supported by the departments of the MRA related to the issue.

5.1.6.4. Be responsible for supervising all medicines-related activities and the control of medicines.

5.1.6.5. Ensure transparent and efficient medicines registration procedures for the country.

5.1.6.6. Have the prerogative of determining which medicines or active ingredients deserve faster processing, subject to the public interest.

5.1.6.7. Compile and maintain an officially approved medicines register that will be reviewed periodically.

5.1.6.8. Determine the classification of premises for the provision of pharmaceutical services in accordance with the therapeutic categories of medicines to be supplied.

5.1.6.9. Determine the classification of medicines in accordance with their therapeutic categories and level of distribution in the public interest.

5.1.6.10. Be provided with adequate resources, infrastructure, and technical support for strengthening national medicines regulation.

5.1.6.11. Maintain one or more inspectorates to monitor all activities in the pharmaceutical sector, except for those inspection duties that have been or shall be assigned to other bodies.

5.1.6.12. Establish and maintain working links with comparable institutions functioning in other countries or operating on a regional or global basis.

5.1.6.13. Assume such other tasks as may be delegated to it by the Government.

5.1.7. Levy fees for the registration and retention of medicines in the medicines register (the fee structure will be reviewed periodically for possible revision).

5.1.8. Use funds generated from medicines registration and licensing activities to cover part of the MRA’s operational costs.

5.2. Registration

5.2.1. Only medicines and other pharmaceuticals that are registered in Afghanistan may be supplied to the pharmaceutical markets in the country, unless otherwise approved by the Minister of Public Health in consultation with the NMFB.

5.2.2. The criteria for the registration of medicines will be based on the scientific evaluation of quality, efficacy, safety, therapeutic advantage, laboratory testing results, and evidence of Good Manufacturing Practice (GMP).

5.2.3. Registration and marketing authorization for medicines and other pharmaceuticals may only be carried out if the procedures, standards, and facilities for manufacturing of medicines and other pharmaceuticals have been evaluated and received prior approval.

5.2.4. A fast-track registration procedure will be established for essential medicines, as appropriate, for both the public and private sectors.

5.2.5. Registration status for each medicine and other pharmaceutical items will be granted for a period of five years, subject to review and renewal as determined by the MRA.

5.2.6. The national MRA will periodically provide and disseminate information to health care professionals and the general public about registered medicines and other pharmaceuticals.

5.2.7. The medicines registration system will be fully computerized and made functional with the appropriate software.

5.2.8. The exchange of information with MRAs of other countries will be on a strictly confidential basis.

5.2.9. Internationally acceptable standards will be adopted for the registration of medicines and other pharmaceuticals in Afghanistan.

5.2.10. The manufacture, exportation, importation, and distribution of unregistered, counterfeit, substandard, or expired medicines and raw materials will not be permitted and will be punishable by law.

5.3. Control and Inspection

5.3.1. Medicines legislation and regulations will be supported by an adequate and effective system for medicines control and inspection.

5.3.2. The national MRA will collaborate and cooperate closely with relevant statutory bodies, agencies, and health professional bodies.

5.3.3. Psychotropic and narcotic medicines control shall conform to the national laws that are relevant, and the requirements of international substance control treaties that are applicable and to which Afghanistan is a signatory.

5.3.4. A permit system for the manufacturing, importation, and exportation of psychotropic and narcotic substances and other controlled medicines will be established accordingly.

5.3.5. Only holders of import and export permits who also have special permission from MoPH for the export and import of medicines and medical devices will be allowed to import or export medicines and other pharmaceuticals.

5.3.6. All consignments of medicines and other pharmaceuticals crossing the national borders will be checked against those documents authorized by the MRA.

5.3.7. The national MRA or MoPH may allow individuals entering Afghanistan to import limited quantities of medicines prescribed for their personal use as per a prescription.

5.3.8. The national MRA will carry out GMP inspections of local pharmaceutical manufacturing plants.

5.3.9. In collaborating with the regulatory agencies of other countries, the national MRA will carry out GMP evaluations of foreign pharmaceutical manufacturing plants.

5.3.10. All premises and vehicles (including carriers by land, air, and sea) inside the country, in which medicines and other pharmaceuticals are contained, will be subject to inspection.

5.3.11. Pharmacists, and any other competent responsible persons, may be authorized to perform some defined inspection activities based on a terms of reference (TORs) after receiving the necessary in-service training.

5.4. Regulation of the Pharmaceutical Profession and Services

5.4.1. As a temporary measure, the registration of pharmacists and the inspection and control of pharmaceutical services will initially be undertaken by the national MRA. When financial and other circumstances permit, the registration of pharmacists and pharmacy assistants will be transferred to a Pharmacy Council to be established by law.

5.4.2. Pharmaceutical services serving the public directly will be provided only in duly licensed or authorized health facilities, including autonomous, state-owned hospitals[*] and in health posts.

[*] Hospitals designated as nonprofit state-owned enterprises as defined in the Hospital Sector Strategy of 2011 (HSS 2011).

5.4.3. Premises supplying "prescription only" medicines to the public will be under the direct supervision of qualified pharmacists.

5.4.4. All providers of pharmaceutical services at any level must be registered with the relevant pharmaceutical professional and regulatory bodies in Afghanistan to enable them to practice.

5.4.5. As to professional pharmaceutical services providers, whether trained inside or outside the country and who are not duly registered in Afghanistan, their documents will have to be authorized by a relevant evaluative body and registered in the MRA before they can practice in the country.

5.5. Control of Premises and Providers

5.5.1. All authorized local manufacturers, importers, exporters, and distributors of medicines and other pharmaceuticals must have duly registered premises in Afghanistan.

5.5.2. Wholesalers and retailers of medicines shall procure or obtain medicines and related products only from manufacturers, importers, and suppliers registered in Afghanistan.

5.5.3. All licenses issued for the local manufacture, importation, exportation, and distribution of medicines and other pharmaceuticals will be reviewed and if acceptable, renewed on a fixed periodic basis, to be determined by the MRA.

5.5.4. The national MRA will develop a comprehensive mechanism for the licensing of premises for the supply of medicines and supervision of service provision, in accordance with the level of care and prevailing conditions in the area.

5.5.5. Therapeutic alliances (group practices) between different health care professionals will be encouraged for the purpose of providing cost-effective, high quality health care for the benefit of the general public.

5.6. Specific Quality Assurance Measures

5.6.1. The National Quality Control Laboratory (NQCL) will be upgraded to increase its capacity for service provision at all levels.

5.6.2. Where necessary, the NQCL operations will be supplemented by establishing a series of peripheral laboratories in various regions that are capable of performing those forms of quality control that are most frequently required. These small laboratories will be managed and supervised by the NQCL.

5.6.3. A medicines quality assurance system will be developed for the entire medicines supply chain.

5.7. Adverse Reaction Monitoring (Pharmacovigilance)

5.7.1. The National Medicines Information Centre (see section 9.2) will be expanded to carry out pharmacovigilance activities, when such capacity can be made available.

5.7.2. Practicing physicians, pharmacists, and nurses as well as patients will be encouraged to submit data to the Centre on suspected adverse reactions or interactions associated with licensed or traditional medicines.

5.7.3. Local manufacturers, exporters, importers, and distributors of medicines and their authorized representatives in Afghanistan will be required to keep records of all adverse reactions and interactions of medicines reported to them and submit such reports to the Pharmacovigilance Unit of the National Medicines Information Centre.

5.7.4. The National Medicines Information Centre will manage medicines-related data collection, analysis, and the dissemination of relevant information on pharmacovigilance to the providers and the general public in an efficient manner. The Centre will provide the MRA with monthly reports of its findings, including significant data received from foreign institutions.

5.7.5. The Pharmacovigilance Unit will establish and maintain close relations, coordination, and cooperation with the relevant international medicines and therapeutics information centers and the WHO Collaborating Centre for International Medicines Monitoring in the monitoring and reporting of adverse medicines reactions.

5.7.6. Suppliers of branded medicines will be required to label their products and packages in accordance with the regulations of the MRA, which will include the generic names of the medicines in larger type displayed above the trade name.

5.7.7. The national MRA will collaborate closely with other country MRAs, international research institutions, and traditional authorities to identify and investigate complementary medicines.

5.7.8. Efforts will be made for traditional/complementary medicines to be evaluated for safety, efficacy, and quality, and if approved, ultimately be included in the national pharmacopeia.

5.7.9. Mechanisms will be established to regulate Internet pharmacy practice in Afghanistan-based operations, as required.

6. LOCAL MANUFACTURE

Introduction

There is currently no pharmaceutical manufacturing plant for active pharmaceutical ingredients in the country, but there are 13 manufacturing plants for finished dosage forms, most privately owned. Afghanistan does not export pharmaceuticals to any degree and does not have a research-based pharmaceutical industry. The bulk of the pharmaceuticals currently in use in Afghanistan are available from foreign producers, many of which offer high quality and dependable production at low cost. The NMP is designed to take these realities into account.

Objective

To encourage and support the local pharmaceutical industry to continuously develop and improve the manufacturing of high-quality essential and complementary medicines needed for Afghanistan and for export.

6.1. Support the Local Manufacturing

6.1.1. The Government will actively encourage local manufacturing companies to produce licensed medicines that are of the same standard of quality and reasonably comparable in terms of cost to the corresponding items from foreign suppliers.

6.1.2. Considering the economic situation of the country, the manufacture of essential medicines by local manufactures is preferable.

6.1.3. Support may involve a degree of preference in procurement, the provision of training, export incentives or tax relief, or other measures that are acceptable in normal commercial practice, regulation, law, and international agreements. The Government may also promote collaboration with other countries to develop local production of raw materials or finished products, where appropriate.

6.1.4. In all decisions related to pharmaceutical affairs, priority will be given to the local production of items.

6.1.5. The Government will support the establishment of industrial parks for local pharmaceutical manufacturing companies.

6.1.6. The Government will seek opportunities and develop strategies to facilitate the export of pharmaceutical products, especially processed herbal products.

6.1.7. The Government is responsible for facilitating forums and any other mechanisms of communication between local and external manufacturers as well as academic centers for the purposes of experience, knowledge, and technology exchanges and export opportunities.

6.2. Traditional Medicines

6.2.1. In consideration of the current widespread use of herbal and other traditional medicines native to Afghanistan, and the trust placed in these products by the general population, the Government will accept the continued production, sale, and use of such medicines, except where evidence emerges that a particular traditional item is either ineffective or detrimental to health.

6.2.2. At the same time, the Government will promote and encourage research into the properties and usefulness of traditional products so that their rational selection and use are facilitated, and integrated into general health care and medical practice, where possible.

6.2.3. The Government will encourage the sustainable cultivation and harvest of potentially beneficial therapeutic plants for the production of complementary medicines.

6.2.4. In furtherance of this policy, the Government will progressively establish a multi-sectorial mechanism to:

6.2.4.1. Develop criteria for the selection of complementary medicines for the health system.

6.2.4.2. Screen all potentially beneficial complementary medicines for therapeutic activity, efficacy, safety, and toxicity.

6.2.4.3. Compile a national database of indigenous plants with proven or alleged medicinal value.

6.2.5. The national MRA will introduce a system for the registration of traditional healers and promote their adherence to a written code of ethics and practice.

6.3. Production and Production Inspection

6.3.1. All manufacturing plants—whether producing licensed or traditional medicines—will be required to ensure the safety, efficacy, and quality of medicines by strictly adhering to recognized guidelines for GMP.

6.3.2. Such plants will be inspected regularly by an inspectorate reporting to the national MRA to ensure compliance with GMP guidelines. A list of registered local manufacturing companies and their produced medicines will be compiled, published, and reviewed by the national MRA at least annually.

7. SELECTION

Objective

To ensure that medicines and related products are safe, efficacious, high quality, and affordable, and that available funding is used to the best advantage, it is necessary to set certain priorities.

The first priority should be to ensure that basic lists of essential medicines that meet these criteria are accessible to all and at all times. WHO defines essential medicines as comprising those "that satisfy the needs of the majority of the population" (http://www.who.int/medicines/services/essmedicines_def/en/). Every country defines its own list of essential medicines in accordance with the health status and requirements of its population. The list will need to be revised periodically to take into account the changing prevalence of new, emerging, or re-emerging diseases and new therapeutic developments.

Beyond this, it will be desirable to make a wider range of alternative or supplementary medicines available to meet less widespread or less urgent needs (to the extent that the economic situation allows).

7.1. Licensed and Essential Medicines

7.1.1. All medicines that are currently approved and registered for use in Afghanistan and have met the criteria for approval defined in Section 5 above will be contained in the licensed medicines list (LML).

7.1.2. Within the LML, the Government, acting through the Minister of Public Health, who is responsible for preparing the requirements of the public sector, will draw up and maintain a more limited list of those items that are considered to meet the WHO criteria for recognition as essential medicines. The essential medicines list (EML) will be periodically reviewed and adapted, as necessary, in line with standard treatment guidelines (STG) and in consultation with all stakeholders.

7.1.3. The selection of medicines for inclusion in the EML will be based on the criteria set by the national MRA in order to reflect:

7.1.3.1. The health needs of the majority of the population.

7.1.3.2. The availability of sufficient scientific evidence to prove their quality, safety, and efficacy.

7.1.3.3. The assessment of cost and effectiveness.

7.1.3.4. The preference for single pharmacologically active ingredient, except where a fixed dose combination offers a clear therapeutic advantage.

7.1.4. The EML will specify the generic name or international non-proprietary name (INN) for each medicine as well as its therapeutic class, dosage forms, and strength, and the level of care at which it may be prescribed in the public sector.

7.1.5. The EML will serve as the principal guideline for the procurement of medicines for use in the public sector, but the Government may extend procurement to certain additional items when the public health situation renders this necessary.

7.1.6. The LML will also serve as the principal guideline for the development of national medicines formularies, the training of health providers, and eligibility for reimbursement under any government-sponsored medical aid or insurance schemes.

7.1.7. The EML will be made available to all health care providers in Afghanistan and any changes made to the EML will be made known through official circulars.

7.1.8. The MRA, in consultation with the health services provision department of MoPH, will prepare the list of medicines required for different levels of health services, which will be circulated for use to all public health facilities after approval by the medicines selection committee.

7.1.9. The Essential Package of Hospital Services (EPHS) and BPHS health facilities shall prepare their lists of required medicines from the EML, and in consideration of the levels and types of services that these facilities provide. The lists can be used in the facilities after their approval by the MRA.

7.1.10. The EML may not contain the specialty requirements of national and specialized hospitals. These facilities can prepare a limited list of specialist requirements that should be on the LML, and attach the list to their formulary list after such lists have received permission of the MRA and approval of the selection committee.

8. SUPPLY

Introduction

Access to essential and complementary medicines is a prerequisite for realizing the right to access health care (IRA MPH 2010). The procurement and supply of medicines should be carried out prudently to ensure that national resources are used with care. Stringent management controls need to be implemented to eliminate or reduce wastage in the medicines supply chain system as well as to avoid any failure in the supply of medicines.

Objective

To make high quality essential and complementary medicines available in adequate quantities to meet the health needs of the population in all parts of Afghanistan at the lowest possible cost.

8.1. Procurement

8.1.1. The principles of Good Procurement Practice will be followed in all procurement activities relating to medicines and medical supplies.

8.1.2. The procurement of medicines for the public sector will be limited to medicines in the EML, unless otherwise approved by the Minister for Public Health in consultation with the NMFB.

8.1.3. The procurement of medicines for the private sector will be limited to medicines in the LML, unless otherwise approved by the Minister for Public Health, in consultation with the NMFB.

8.1.4. Procurement will be aimed at securing value for money products of acceptable quality to make the best possible use of available funds.

8.1.5. Procurement of medicines for the public sector will generally be undertaken or supervised/controlled at the national level through national and international competitive tender, performance-based contracting, or other methods in accordance with law.

8.1.6. The evaluation and procurement of essential medicines will be in accordance with the WHO certification scheme on the quality of pharmaceutical products moving in international commerce.

8.1.7. Companies registered in Afghanistan will be given preference, provided such preferences are permitted by law, regulation, and related agreements governing the procurement of medicines, and provided that the companies are fully competitive in terms of quality, equal value for money, and reliability of supply.

8.1.8. The Government will actively promote efficiency in procurement at all levels by ensuring the involvement of qualified personnel and facilities at all levels, whether operating in the public or private sectors.

8.1.9. The Government will establish an autonomous, integrated, and fully computerized information system for the central and lower supply levels to support procurement.

8.1.10. Market intelligence capability will be developed to improve procurement at the national level.

8.1.11. Procedures will be developed for the independent procurement of medicines by autonomous hospitals recognized as nonprofit state-owned enterprises and for the effective monitoring of procurement by these institutes (HSS 2011).

8.1.12. Procurement will be subject to the rules and procedures set out by the Procurement Policy Unit of the Ministry of Finance (IRA MF 2009), except where exemptions may have been granted to meet certain specific needs arising in the health sector.

8.2. Donations

8.2.1. The Government will develop and implement a national guideline on medicines donation, taking into account internationally accepted standards.

8.2.2. The donation of medicines must comply with the above policy.

8.2.3. Donated medicines must meet all of the following criteria:

8.2.3.1. Be certified by the MRA of the exporting country in accordance with the WHO certification scheme on the quality of pharmaceutical products moving in international commerce.

8.2.3.2. Be listed on the EML of Afghanistan.

8.2.3.3. Have at least 12 months shelf life or, if the normal shelf life is less than 12 months, have at least 75% of the remaining shelf life.

8.2.3.4. Be labeled in English.

8.2.3.5. Be authorized by the Minister for Public Health in consultation with the national MRA.

8.3. Storage

8.3.1. The Government will seek to ensure the provision and maintenance of adequately sized, suitably constructed, well equipped, and secure storage facilities at all levels of the public sector medicines distribution system.

8.3.2. Storage facilities will be subject to inspection based on recognized standards to ensure their continued adequacy.

8.3.3. Regular and periodic checking and monitoring of stored medicines will be performed by the pharmaceutical personnel in charge of the storage facilities at all levels and by inspectors reporting to the MRA.

8.3.4. The Government will ensure that adequate numbers of suitably trained pharmaceutical personnel are recruited to manage public and private sector storage facilities.

8.3.5. Pharmaceutical personnel will be involved in the planning and renovation of medicines storage facilities at all levels.

8.3.6. Deteriorated, obsolete, expired, damaged, banned, and unwholesome medicines will be properly documented and segregated in all warehouses.

8.3.7. Such deteriorated, obsolete, expired, damaged, banned, and unwholesome medicines will be identified and separated from the main medicines, recalled, and then disposed of in accordance with national guidelines, under the supervision of the MRA, and in such a way that precludes their use by any person, and with minimal environmental impact.

8.4. Inventory Control and Monitoring of Supply

8.4.1. Computerized ordering, dispensing, and inventory control systems will be introduced at all levels, and staff will be trained in their use.

8.4.2. Standard operating procedures will be developed to ensure effective inventory control procedures and accountability at all levels of the public medicines supply system.

8.4.3. Systematic, practical, and accurate procedures for the quantification and regular reporting on medicines consumption will be introduced and maintained to facilitate the national procurement process and expenditures related to monitoring medicines.

8.4.4. The adequacy and appropriateness of medicines supply at all levels shall be regularly monitored in accordance with the standards prescribed in the current edition of the BPHS and EPHS.

8.5. Distribution

8.5.1. Medicines shall only be distributed through authorized institutions in the public, parastatal, and private sectors. The Government will develop a common set of standards for all institutions undertaking storage and distribution of medicines.

8.5.2. Multiple distribution mechanisms using the resources of the public, private, and NGO sectors will be employed to ensure a reliable supply of essential medicines. In general, the authorized institution providing the medicines will also undertake the storage and distribution of those medicines. The central medical store will be responsible for managing the distribution of directly government-funded medicines in the public sector. Satellite warehouses may be established, where necessary, to ensure efficient distribution to all parts of the country.

8.5.3. Distribution of medicines will be regularly monitored in the public and private sectors.

8.5.4. Health facilities distributing medicines at any level will keep records of all medicines at the facilities at all times.

8.5.5. The Government will facilitate efficient transportation and communication, and provide sufficient personnel to maintain an efficient public sector distribution system.

8.5.6. The Government will promote decentralization of the public sector distribution system, as appropriate.

8.5.7. The Government will institute an efficient and practical system for the early identification, collection, and redistribution of excess stocks of medicines and other pharmaceuticals.

8.5.8. The Government will encourage the establishment of special mechanisms for the supply of medicines to underserved communities.

8.5.9. The Government will ensure the creation of facilities for the destruction of expired, illegal, contaminated, or otherwise unwanted medicines in a safe and environmentally acceptable manner.

9. RATIONAL MEDICINES USE

Introduction

Rational medicines use (RMU) requires that people receive medicines appropriate to their clinical needs, in doses that meet their individual requirements for an adequate period of time, and at the lowest cost to them and the community, along with the requisite information. Irrational use of medicines may unnecessarily prolong or even cause ill-health and suffering, and result in wastage of limited resources.

The emergence of new and infectious diseases managed with fixed-dose combination medicines and demanding lifelong treatment makes the promotion of adherence to treatment and correct use of medicines crucial. It is therefore imperative to strengthen therapeutic governance to curb the emergence of antimicrobial resistance, medicine abuse, dependence, and tolerance.

Objective

To promote good prescribing and dispensing practices by health care providers as well as informed use of medicines by the community.

9.1. Awareness, Education, Training, and Rational Medicine Use

9.1.1. All health workers and the general public will be educated on the dangers of irrational use of medicines and medicines abuse.

9.1.2. Stringent educational and regulatory measures will be instituted to minimize the negative effects of medicines advertising and commercial information.

9.1.3. Curricula for all educational programs for health personnel will be revised to incorporate sufficient exposure to the concepts of RMU and related topics.

9.1.4. Health professional bodies will be encouraged to provide mentorship and professional guidance to undergraduates, interns, and colleagues in their respective professions to promote RMU.

9.1.5. Mechanisms will be developed to promote informed use of medicines in the communities and schools.

9.1.6. A team approach to patient care will be encouraged and supported to promote systematic case management in all health facilities in Afghanistan.

9.1.7. RMU indicators will be periodically monitored at service delivery points throughout the country.

9.1.8. The Minister of Public Health will designate an advisory body to promote RMU by all appropriate means and to monitor progress towards this goal.

9.2. Information

9.2.1. The Government will support, reinforce, and equip the National Medicines Information Centre with public funding.

9.2.2. The National Medicines Information Centre will:

9.2.2.1. Periodically produce a medicines information bulletin or newsletter and ensure its distribution throughout the health system and to all relevant stakeholders.

9.2.2.2. Ensure rapid communication through the media of important new information relating to safe medicines use.

9.2.2.3. Provide both health workers and the general public with specific information relating to medicines, on request.

9.2.2.4. When needed, assist the MRA to obtain information it needs for its operations.

9.2.2.5. Promote the unrestricted sharing of medicines information among professional bodies and health care practitioners.

9.2.3. When appropriate and necessary, the Government will ensure the establishment of satellite medicines information and pharmacovigilance centers throughout the country.

9.3. Rational Prescribing

9.3.1. All medicines, including approved complementary medicines, shall be prescribed by generic or approved names, and in accordance with Good Prescribing Practice.

9.3.2. Mechanisms will be developed to regularly monitor and assess prescribing practices in both the public and private sectors and use the findings to ensure cost-effective and rational prescribing.

9.3.3. The Government will promote the rational prescribing of medicines that have scientifically proven therapeutic efficacy in accordance with the National Standard Treatment Guidelines (NSTG) for the Primary Level of Afghanistan.

9.3.4. The NSTG will be reviewed periodically and disseminated to all health care professionals.

9.3.5. The medicines listed in the NSTG will guide the selection of medicines for the EML.

9.3.6. All health care providers directly involved in the diagnosis, prescribing, and dispensing of medicines will be regularly trained on the NSTG.

9.4. Rational Dispensing

9.4.1. All medicines, including approved complementary medicines, will be dispensed and labeled using generic or approved names and in accordance with Good Dispensing Practice (GDP).

9.4.2. The Government will promote the adequate provision of packaging and labeling materials at all dispensaries in public and private health facilities to facilitate GDP.

9.4.3. The Government will promote the production of a cross index of generic and proprietary names, and will facilitate the making of information available for all medicines on the Afghanistan market.

9.4.4. Pharmacists in both the public and private sectors will be allowed to substitute identical generic medicines for prescribed branded medicines.

9.4.5. Pharmacists handling prescriptions for branded medicines will, before dispensing such medicines, inform the client about available, cheaper generic alternatives.

9.4.6. Prescribers are not allowed to reject any generic medicine distributed by a pharmacist in favor of a branded medicine.

9.4.7. The MRA will promote the inclusion of the following minimum information on the label of a dispensed medicine:

9.4.7.1. Name of pharmacy or health facility
9.4.7.2. Date dispensed
9.4.7.3. Name of client
9.4.7.4. Generic name of active ingredient
9.4.7.5. Strength of active ingredient
9.4.7.6. Quantity of medicine dispensed
9.4.7.7. Complete dosage regimen in written or graphic form
9.4.7.8. Prescription number
9.4.7.9. Latest date for use—the "use before" date
9.4.7.10. Any relevant special instructions

9.4.8. Dispensing will be performed by pharmacists, pharmacy assistants, and by holders of a valid dispensing license.

9.4.9. Premises where dispensing activities are performed will be inspected regularly and in accordance with law to ensure that all legal provisions are being met.

9.4.10. Counseling on the use of medicines, potential side effects, and adherence to therapy will be promoted as part of the dispensing process in all health facilities.

9.4.11. Medicines will not be dispensed based on prescriptions generated via the internet or telephone, except in accordance with approved national guidelines.

9.5. Medicines and Therapeutics Committees

9.5.1. Medicines and Therapeutics Committees (MTC) will be established and made functional at national, provincial, district, and health institution levels in the public and private sectors.

9.5.2. All MTCs will implement strategies to promote rational, efficient, and cost-effective supply and use of medicines at all health care levels.

9.5.3. MTCs will be responsible for:

9.5.3.1. Assessing medicines and medical supply requirements for their respective levels.

9.5.3.2. Managing and monitoring medicines-related budgets.

9.5.3.3. Monitoring compliance with NSTG and overall medicines use.

9.5.3.4. Developing appropriate interventions for improved therapeutics.

9.5.3.5. Facilitating the provision of relevant and up-to-date medicines use information for prescribers and dispensers.

9.5.3.6. Planning for measures to be employed in case of medicine shortage or overstock.

9.5.3.7. Developing local formularies and treatment protocols in line with the LML (in the private sector), EML (in the public sector), the STGs, and MoPH policies.

9.5.3.8. Initiating the process of requesting approval for purchasing medicines outside the EML, with clear reasons and justifications.

9.5.3.9. Instituting appropriate measures for the prompt, safe, and efficient disposal of damaged, deteriorated, expired, or unwholesome medicines.

9.5.3.10. Coordinating reports on suspected medicines-related adverse events and reporting of such events to the national medicines information and pharmacovigilance center.

9.5.3.11. Making recommendations for the inclusion/exclusion of medicines and other pharmaceuticals for the LML and EML.

9.6. Antimicrobial Resistance

9.6.1. The Government is responsible for enforcing appropriate legislation and guidelines to reduce the number of cases of antimicrobial resistance (AMR) and to manage the AMR cases appropriately.

9.6.2. Mechanisms will be developed to effectively monitor and contain AMR, provide access to microbiological laboratories, and implement new interventions.

9.6.3. Training programs will be held for prescribers and dispensers so that they can then educate patients on antimicrobial use and the importance of adherence to prescribed treatments.

10. MEDICINES FOR NEW, EMERGING, AND RE-EMERGING DISEASES

Introduction

Public health concerns continue to be aggravated by challenges presented by new and emerging diseases, while re-emerging diseases, such as multidrug-resistant tuberculosis and extensively drug-resistant tuberculosis, also pose new challenges. Such diseases become major national issues because their treatment and management usually require expensive medicines, which may be out of reach of most people. The medicines are usually new on the global market and constitute a serious financial burden on the Government to make them available to the public.

Objective

To provide safe, quality assured, and highly cost-effective medicines for the adequate management and control of new, emerging, and re-emerging diseases.

10.1. Medicines for New, Emerging, and Re-Emerging Diseases

10.1.1. The Government will work to ensure the quality, safety, and rational use of new medicines in both the public and private sectors at all times.

10.1.2. The Government will develop a system to provide essential and complementary medicines for new, emerging, and re-emerging diseases posing challenges for both the public and private sectors.

10.1.3. The Government will collaborate with the relevant international bodies to mobilize resources for new essential medicines to meet national needs.

11. AFFORDABILITY, FINANCING, AND PRICING

Introduction

Financial policies should reflect the need for medicines to be both accessible and affordable for the entire population. For this ideal to be attained and consistently maintained, financial policies need to be developed covering all components of the supply chain, from the procurement of medicines by the health system to the price paid (by an individual or the health system) when a medicine is delivered to the ultimate user.

It is MoPH's responsibility, as defined in the National Health Policy and Strategy, to ensure stable and adequate financing for health care as a whole and despite the growing challenges. The Ministry should ensure that the financing of medicines supply is fairly shared between the Government and consumers and that stringent price control is maintained and wastage reduced. At all times, the Ministry should ensure that: spending is in line with priorities; there is sufficient transparency in the allocation of financial resources; the various sources of funding are coordinated; and the different mechanisms for financing the delivery of health services are monitored for their cost-efficiency and acceptability.

Objective

To mobilize and provide adequate funds for the sustainable supply of essential and complementary medicines to meet national health needs.

11.1. Sustainable Financing

11.1.1. The Government will endeavor at all times to provide adequate funds, and with a long-term commitment, for the procurement of essential and complementary medicines for all public health institutions.

11.1.2. Since the financial demands posed by the medicines sector necessarily competes with needs of other sectors funded by the public budget, where feasible, MoPH will propose selective cost/benefit studies to document and justify the need for financing in certain areas.

11.1.3. Funds allocated for the supply of medicines will be used efficiently and judiciously in the ultimate interest of the general public.

11.1.4. All possible lawful sources of funding will be explored to generate funds and guarantee an adequate supply of essential medicines for all people in Afghanistan.

11.1.5. In the development of protocols and selection of treatment methods and the related medicines, the most accessible and affordable alternatives should be prioritized.

11.1.6. The development of insurance systems, either public or private, to cover medicines costs will be promoted.

11.1.7. The Government will build public-private partnerships to explore and develop alternative financing mechanisms for the efficient provision of pharmaceutical services throughout the country.

11.1.8. Inasmuch as possible, the Government will make good use of the flexibilities provided under the World Trade Organization's (WTO) agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) to reduce the financial burden of essential medicines.

11.1.9. Stringent financial control measures will be instituted at all levels to promote the efficient use of funds for the provision of pharmaceutical services.

11.1.10. Regular and periodic budgeting for pharmaceutical services, in accordance with developed guidelines, will be enforced to facilitate the equitable allocation of funds.

11.1.11. Pharmacists, managers of pharmaceutical services, and other health care providers directly involved in pharmaceutical services in both the public and private sectors will be trained and retrained in financial and data management to promote prudent practices and efficiency.

11.2.Pricing Structure

11.2.1. In collaboration with the private sector, the Government will develop comprehensive medicines pricing policy aimed at making essential and complementary medicines affordable at all levels and in all sectors. This will involve both a critical approach to the costs of initial procurement and the imposition of standards regarding the margins earned by manufacturers, importers, wholesalers, and retailers.

11.2.2. The Government will ensure total transparency in the medicines pricing structure, guided by internal and external reference prices.

11.2.3. The Government will critically examine the extent to which existing taxes, tariffs, and duties may impose an avoidable burden on the system (and ultimately on the user) for providing medicines and will propose corrective measures, if necessary.

11.2.4. A system will be established to determine which medicines for curative, preventive, and palliative health services will be provided free of charge at public health facilities.

11.2.5. Patients' contributions to the cost of treatment and medicines will be in accordance with prevailing national laws and policies.

11.3. Monitoring Prices

11.3.1. A national multi-sectorial system will be developed for monitoring and evaluation (M&E) of the medicines pricing policy at all levels of the distribution chain.

11.3.2. Accurate data on the pharmaceutical market in Afghanistan, including private household expenditure on medicines, will be compiled and analyzed regularly to determine the effects of the medicines pricing policy and to plan interventions.

11.4. Promoting the Use of Generics

11.4.1. The Government will promote the use of generic names or INN in medicines procurement, distribution, and prescribing, as well as the dissemination of medicines-related information using generic names at all levels of the health system.

11.4.2. The Government will promote the use of complementary and alternative multi-sourcing of pharmaceutical products and appropriate incentive packages to reap the advantages of competitive pricing for medicines and to curtail expenditures.

11.4.3. Health workers, including doctors and pharmacists, will be encouraged to explain the acceptability and cost benefits of generic products to patients. When a product has been prescribed under a brand name, the retail pharmacist will be permitted to dispense a generic equivalent of the same medicine if it is available and the prescriber does not reject it.

12. PHARMACEUTICAL WASTE DISPOSAL

Introduction

The current volume of medicines used in Afghanistan is low by world standards. Any system of disposal should be developed in keeping with the realities of current volumes and especially in light of the country's economic activity levels.

WHO guidelines, in conjunction with the Afghanistan Environmental Protection Agency, will be used as the guiding basis for the development of effective disposal policies.

As a guiding principle for budgeting purposes, 1% of the cost of all medicines to be provided in Afghanistan should be allocated for pharmaceutical product waste management activities. The goal of this section of the NMP is to protect the health of the public from potential harm that may result from the unsafe or ineffective disposal of expired, damaged, or otherwise unwanted medical items, including pharmaceuticals.

Objective

To institute and maintain a system that will ensure the safe, cost effective, and controlled disposal or destruction of such items.

12.1. Disposal of Expired, Damaged, Falsified/Counterfeit, or Otherwise Unwanted Medicines and Medical Supplies

12.1.1. The GDPA, in cooperation with relevant agencies, will be responsible for establishing national guidelines for the disposal of these items in the context of an overall national health care waste management plan.

12.1.2. In accordance with clause 9.5.3.9 of this policy, the MTCs at all levels will be responsible for the implementation of the national disposal guidelines as they relate to pharmaceutical products.

12.1.3. The national guidelines for disposal of pharmaceutical products will include safe and cost-effective strategies and procedures for:

- Elements to be included in national pharmaceutical training curricula at academic institutions
- Training programs for workers handling disposal items
- Identification of medicines and medical supplies waste
- Handling of waste products
- Collection
- Segregation of different product types
- Storage
- Transport
- Disposal/destruction
- Record keeping

12.1.4. The GDPA will be responsible for systematically monitoring and evaluating the implementation of the medicines and medical supplies waste management plan and making any necessary amendments to the national guidelines.

13. GLOBAL TRADE IN PHARMACEUTICALS AND INTELLECTUAL PROPERTY RIGHTS

Introduction

The TRIPS agreement, a major instrument created by the WTO member states for the health sector, introduces minimum global standards for protecting and enforcing intellectual property rights, including pharmaceutical products and processes. The TRIPS agreement can affect access to medicines required for diseases of public health importance. Governments are obliged have their legislation on intellectual property rights conform to the TRIPS agreement. However, a number of special provisions of the agreement have been adopted to help developing countries comply without due hardship on developing countries (WHO 2010).

Objective

To develop legislation, regulations, and policies that maintain a balance between the minimum standards of intellectual property rights protection and the needs of public health, especially as regarding the supply of essential medicines.

13.1. Development of Appropriate Legislation

13.1.1. The Government will take full advantage of the TRIPS agreement safeguards to promote and maintain public health and to ensure access to essential medicines, while seeking to implement the regulations relating to intellectual property rights.

13.1.2. The Government will actively collaborate with the relevant ministries, agencies, departments, and NGOs in the area of intellectual property rights in developing and reviewing the national legal framework that promotes access to essential medicines.

14. ADVERTISING AND PROMOTION

Introduction

Advertising and promoting medicines can be a useful means of disseminating scientific information to health care providers and the community. However, the commercial element inherent in this activity commonly leads to certain unethical and unprofessional practices for the purpose of gaining individual or group benefits, which can result in damage to individuals and the community at large. Stringent control measures are necessary to protect the general public.

Objective

To maintain high professional and ethical standards in advertising and the promotion of essential and complementary medicines to safeguard the general public

14.1. Responsible Advertising

14.1.1. The Government will develop a national policy on the advertising and marketing of medicines, reflecting the sociocultural needs of the country.

14.1.2. Advertising and marketing of medicines shall comply with national policies and with the WHO Ethical Criteria for Medicinal Drug Promotion (http://apps.who.int/medicinedocs/documents/whozip08e/whozip08e.pdf, http://apps.who.int/medicinedocs/en/m/abstract/Jwhozip08e/).

14.1.3. National ethical criteria for medicines promotion and advertising will be established and published periodically for distribution to all interested parties.

14.1.4. All medicines to be advertised or promoted will be registered with the national MRA.

14.1.5. All advertisements and promotion of medicines will be of high professional and ethical standards.

14.1.6. Labeling and advertising of medicines will be in conformity with scientifically established evidence, in national languages, culturally acceptable, and in line with approved package inserts.

14.1.7. Medicines promotional activities will be in line with the NMP objectives.

14.1.8. Whenever the brand name of a medicine is used in any form of promotional or educational material, including electronic and print media advertising, the generic name of the medicine will be given due prominence.

Medicines advertising will always be educational in purpose. Public advertising will be restricted to non-prescription (over-the-counter) medicines only. When

possible and practical, medicines advertising campaigns will be targeted at health professionals rather than the general public.

14.1.9. The promotion and advertising of prescription-only medicines will be restricted to professional medical, pharmaceutical, dental, veterinary, or nursing publications.

14.1.10. Encouragement of health practitioners who may have personal, financial, or material interests in the prescribing and dispensing of medicines will be deemed unethical and unprofessional by all parties involved.

14.1.11. Scientific research results and materials will not be misused to promote medicines.

14.1.12. The national MRA will examine and approve all public advertising materials on medicines before they are used in print or electronic media.

14.1.13. No advertisement for a medicine will contain a statement that deviates from the evidence submitted in the application for registration, where such evidence has been accepted by the national MRA.

14.1.14. Using children and women in advertising/promotional media in a socially or culturally unacceptable manner will not be permitted.

14.1.15. Targeting children and women in advertisements for unapproved, unnecessary, untested, or potentially harmful medicines will not be permitted.

14.1.16. The MRA will carefully monitor medicines advertising and promotional activities to ensure that they conform to national scientific, professional, and ethical standards.

14.1.17. Mechanisms will be developed for members of the public and health professionals to report inappropriate, fraudulent, or illegal medicines advertisements to the national MRA.

15. HUMAN RESOURCE DEVELOPMENT AND PHARMACY EDUCATION

Introduction

Sustained human resource development (HRD) of pharmacy is crucial to the attainment of efficient governance and management of pharmaceutical services, in particular, and of health services, in general. Robust HRD policies facilitate the right skills mix and the optimal use of available expertise at all levels. HRD includes the policies and strategies chosen to ensure that there are enough trained and motivated personnel available to implement all components of the NMP.

The Afghanistan National Health Policy and Strategy states that MoPH is committed to using a comprehensive approach to HRD to address the production, deployment, and retention of an appropriately trained health workforce that possesses the varied skills needed to deliver affordable and equitable packages of health services.

Objective

To build the human resource capacity of pharmaceutical services to ensure efficiency, prudent use of resources, and good therapeutic outcomes

15.1. Pharmaceutical Human Resource Development

15.1.1. The Government will carry out a periodic medium-to-long-term needs assessment of pharmaceutical staff at all levels in both the public and private sectors, and implement the recommendations emerging from this assessment.

15.1.2. The Government will develop and implement needs based pre-service and in-service programs to train pharmacists and pharmacy assistants inside and outside the country.

15.1.3. The Government will create an enabling environment for the promotion of pharmacy education and training, especially relating to university level training of graduate pharmacists, and will seek to ensure that the principles of this NMP are incorporated into all future pharmacy trainings.

15.1.4. Health professional bodies, academic bodies, tertiary educational institutions, and colleges will be encouraged to include the essential medicines concept, RMU, financial management, and other relevant issues of this policy in their curricula for training health care providers.

15.1.5. A systematic and comprehensive program of in-service training and continuing professional development will be developed and implemented, emphasizing regulation, quality assurance, and pharmaceutical management.

15.1.6. A comprehensive career development structure will be designed for pharmacists and other pharmaceutical service providers to facilitate professional development and motivate staff.

15.1.7. The Government will create the enabling environment for the recruitment and retention of qualified pharmaceutical service providers throughout the country.

15.1.8. Pharmacists and pharmaceutical service providers in rural and underserved areas will be given preference in government bursaries for studies in pharmacy and other related courses.

16. RESEARCH AND DEVELOPMENT

Introduction

Operational research and development (R&D) facilitates the implementation, monitoring, and evaluation of different aspects of the medicines policy. It is an essential tool for assessing the impact of the medicines policy on national health systems and service delivery by studying the economics of medicines supply, identifying problems related to prescribing and dispensing, and understanding the sociocultural aspects of medicines use.

According to the National Health Policy and Strategy, MoPH is committed to encouraging relevant, useful research that can assist evidence-based decision making and the formulation of new policies, strategies, and plans. A priority is nationally-led health systems research that is conducted in collaboration with international bodies.

Objective

To promote operational R&D activities that facilitate implementation, monitoring, and evaluation of the NMP 2013-2019

16.1. Research and Development in Pharmaceutical Management

16.1.1. The Government will promote the development of multidisciplinary operational research and training of research personnel for the relevant areas of pharmaceutical services, such as:

16.1.1.1. Impact of the NMP on the national health system and economy
16.1.1.2. Pharmacoeconomics of medicine supply and use
16.1.1.3. Prescribing and dispensing practices at different levels of the health system
16.1.1.4. Social and cultural aspects of medicines use vis-à-vis self-medication, acceptability of pharmaceutical services, and attitudes of medicines users

16.2. Technical and Scientific Research

16.2.1. Clinical trials shall only be performed subject to the approval of the national MRA in collaboration with the relevant technical committee, and shall be in compliance with the WHO Guidelines on Good Clinical Practice (http://apps.who.int/medicinedocs/pdf/whozip13e/whozip13e.pdf).

16.2.2. Exploratory and developmental research into local raw materials and herbal products as sources for new medicines will be encouraged to achieve the objective of increased local production of essential medicines through the promotion of local manufacturing capability.

16.2.3. The Government will establish a scientific and technical institute for research and development of medicines and will provide support for its activities.

16.2.4. Because of the limited availability of funds for research, priority will be given to major pharmaceutical challenges in accordance with the goals and objectives of the NMP.

16.2.5. The Government will promote the exchange of research findings with other countries and with international agencies.

16.2.6. The Government will encourage and support the participation of local researchers and research institutions in international medicines research activities.

17. TECHNICAL COOPERATION

Introduction

Global technical cooperation and assistance constitute a synergistic approach to meeting the challenges of diseases of public health importance. It provides a platform for the exchange of various resources when developing pharmaceutical services within the context of the national health agenda.

The National Health Policy and Strategy promotes effective partnerships and collaboration with all stakeholders sector-wide. MoPH is committed to working in partnership with other stakeholders, and will sustain this through both formal and informal mechanisms.

Objective

To mobilize and optimize resource utilization through the efficient coordination and harmonization of technical cooperation for the purposes of pharmaceutical systems strengthening, governance, and management

17.1. Pattern of Technical Cooperation

17.1.1. The Government will strengthen and broaden ongoing bilateral and multilateral technical cooperation and assistance in the national interest.

17.1.2. The Government will establish new links with international organizations for national development purposes, as appropriate.

17.1.3. International cooperation and technical assistance will be guided by the findings of M&E activities for the NMP.

17.1.4. The focus of international cooperation and technical assistance will always be on priority areas where high impact can be achieved.

17.1.5. Possible areas of technical cooperation and assistance will include, but are not limited to, the following:

- 17.1.5.1. Strengthening pharmaceutical systems, governance, and management
- 17.1.5.2. Regulation
- 17.1.5.3. Quality assurance
- 17.1.5.4. Development of standard dossiers for essential generic medicines formulations
- 17.1.5.5. Medicines information and pharmacovigilance
- 17.1.5.6. Medicines quality surveillance and GMP inspections
- 17.1.5.7. Improving access to essential medicines
- 17.1.5.8. Human resources development and training for pharmaceutical service delivery
- 17.1.5.9. Implementation of international narcotic medicines control treaties

17.1.5.10. Containing the emergence of AMR as well as new and re-emerging diseases
17.1.5.11. R&D in pharmaceutical services and therapeutics
17.1.5.12. R&D in complementary medicines
17.1.5.13. Coordination of the response to emergency situations

17.1.6. The guidelines and recommendations of the WHO, United Nations Medicines Control Program, and other relevant international organizations on technical cooperation will be adopted and implemented, as appropriate.

18. POLICY IMPLEMENTATION

Introduction

The successful implementation of the NMP 2013-2019 requires a multi-sectorial approach and the full commitment of the Government and all stakeholders. The Government recognizes its pivotal role and shall therefore provide the necessary logistics and funds, and support MoPH and relevant organizations to fully implement activities derived from this policy.

The policy requires an accompanying national pharmaceutical master plan to make it operational. The master plan will define the various activities, timelines, and resources needed to accomplish the policy statements based on set priorities.

Objective

To make the NMP 2013-2019 implementable in an efficient and prudent manner within an acceptable time frame through the establishment of appropriate systems, structures, and procedures.

18.1. Implementation Plan

18.1.1. A National Pharmaceutical Master Plan (NPMP) will be developed and adopted to facilitate the implementation of this NMP.

18.1.2. The NPMP will define priority areas and outline short-, medium-, and long-term action plans with defined activities, budgets, time frames, responsibilities, and expected outcomes and outputs, as appropriate.

18.1.3. The NPMP will take into consideration experiences and lessons learned from the implementation of the previous policy and all activities carried out in the pharmaceutical sector.

18.1.4. The national MRA (which is the fully developed structure of the current GDPA) will lead the coordination and implementation of this NMP and its accompanying NPMP.

18.1.5. The Government will facilitate the smooth implementation of this NMP.

19. MONITORING AND EVALUATION

Introduction

An effective M&E system facilitates objective data and information gathering for reporting progress and resource mobilization. M&E provide useful feedback information for objective assessment and informed management decisions.

Key issues include monitoring of the pharmaceutical sector through regular indicator-based surveys, and independent external evaluation of the policy's impact on all sectors of the national economy. Systematic and regular monitoring provides the platform for continuous review that shows how planned activities are being implemented and indicates how targets are being met.

The National Health Policy and Strategy promotes mechanisms to ensure the availability, coordination, distribution, and use of accurate, reliable, user-friendly health information in the design, implementation, and M&E of health services and other related activities.

Objective

To develop a yearly M&E plan that will facilitate the assessment of the performance of the NMP 2013-2019 implementation, in accordance with established strategies, objectives, and activities in the pharmaceutical master plan.

19.1. M&E Mechanisms

19.1.1. A comprehensive M&E system clearly stating the sector-wide indicators will be developed to periodically assess the performance of this NMP for informed management interventions.

19.1.2. The efficiency and effectiveness of the policy will be evaluated periodically, and strategies and activities will be adjusted, as necessary.

19.1.3. The Government will use the findings of M&E as a guide to set priorities, strengthen those strategies that will have the best impact, synchronize policy, and determine future areas of international cooperation and technical assistance.

19.1.4. The national MRA will lead the M&E of the NMP and its accompanying NPMP.

GLOSSARY

Active pharmaceutical ingredient: A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a therapeutically active compound (ingredient).

Adverse medicines reaction (adverse drug reaction): A response to a pharmaceutical product that is harmful and unintended and that occurs at doses normally used or tested in humans for prophylaxis, diagnosis, or treatment of disease, or for the modification of physiological function.

Agreement on Trade-related Aspects of Intellectual Property Rights: An international agreement administered by the WTO that sets down minimum standards for many forms of intellectual property regulation as applied to nationals of other WTO Members, with the goal "to promote access to medicines for all."

Basic package of health services: Standardized basic services that provide the core of service delivery in all primary health care facilities.

Counterfeit medicine: A medicine that is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging.

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

Essential medicines list: A list of medicines approved for use in public sector health facilities.

Essential medicines: Medicines that satisfy the priority health care needs of the population.

Essential package of hospital services: The necessary elements of service mix, staff, facilities, equipment, medicines, and consumables for each type of hospital at each level, which satisfy the public health needs through hospital services provision.

Ethical criteria for medicinal promotion: Criteria prepared by an international group of experts to give manufacturers, distributors, the promotion industry, prescribers, and consumer groups a framework to ensure that promotional practices are in keeping with acceptable ethical standards.

Fast-track registration procedure: A system to prioritize and expedite the processing of applications for registration of pharmaceutical products.

National Food and Medicines Board: The NMFB is a body that advises, coordinates, oversees, and accelerates medicines and food-related activities, and implements basic principles on affairs related to the regulation of pharmaceuticals, medical devices, cosmetics, sanitation equipment, and traditional pharmaceuticals (medicines) to ensure their safety, quality, efficacy and effectiveness. It also ensures the safety and quality of food products and

prevents their unnecessary and unsafe manufacture, importation, distribution, sale, and use.

Generic name: A unique name identifying a particular pharmaceutical substance. Generic names are officially assigned by international medicines nomenclature commissions and nowadays mostly conform to those assigned by the WHO program on the selection of INN.

Generic products: Products marketed under a non-proprietary or generic name rather than a proprietary or brand name, often at a cheaper price.

Good Clinical Practice: A standard for clinical studies that encompasses the design, conduct, monitoring, termination, audit, analyses, reporting, and documentation of the studies, ensures that the studies are scientifically and ethically sound, and that the clinical properties of the pharmaceutical product under investigation are properly documented.

Good Distribution Practice: Are standard practices for activities related to the distribution of medicines. They are part of QA, ensuring the preservation and sustainability of the quality of medicine products during their distribution,

Good Manufacturing Practices: Are standard practices for activities related to the manufacturing of medicine. They are part of a pharmaceutical QA system, ensuring that products are consistently manufactured, produced, and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization.

Good Pharmacy Practice: The supply of medication and other health care products of assured quality, appropriate information and advice for the patient, and monitoring the effects of their use.

Good Storage Practice: A documented system and procedures for receiving, arranging, storing, and transporting pharmaceuticals so as to maintain the quality of the products throughout the handling processes.

Good Distribution Practices: Part of QA that ensures that the quality of pharmaceutical products is maintained by means of adequate control throughout the numerous activities that occur during the trade and the distribution process.

Government: The Islamic Republic of Afghanistan.

Health practitioner and professional: One who is fully licensed and approved by the relevant national authorities to practice medicine or an allied health profession, such as nursing, pharmacy, and radiography on humans.

International non-proprietary name: The shortened scientific name (also known as the generic name) of a pharmaceutical substance assigned by the WHO program on the selection of INNs. The INN is recognized worldwide.

Licensed medicines list: All medicines that are approved for use in Afghanistan at different levels of the health system.

Licensing authority: General name for any statutory body delegated by the Government to register health practitioners and to regulate their professional practice.

National medicines regulatory authority: An entity/organization/structure in charge of the administration of medicines regulation, including at least one of the following regulatory activities:

- Issuing marketing authorization for new products and dealing with variation of existing products
- Testing the quality of products
- Monitoring adverse drug reaction and events
- Inspecting and licensing of manufacturers, wholesalers, and distribution channels and related enforcement operations
- Controlling medicines promotion and advertisement
- Providing medicines information and promotion of rational use of medicines
- Other tasks relevant to pharmaceutical services

Narcotic: Natural or chemical compounds that cause abnormal changes in the function of the central nervous system and consciousness level. They create increasing psychological and physiological dependency or addiction in humans, with the consequence of adverse effects on human physical, mental, and social performance.

Over-the-counter medicines: Medicines that are generally regarded as safe for the consumer for use by following the required label directions and warnings, and which may be purchased without a prescription.

Pharmaceutical product: Any medicine, medicinal product, herbal medicine, and any substance included in any publication mentioned in the Medicines Laws, or any substance or mixture of substances prepared, sold, or represented for use in the diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state, or symptoms thereof, or restoring, correcting, or modifying organic functions in humans.

Pharmaceutical sector: The sector of health care concerned with the knowledge or art of pharmacy and its practice according to specific rules and formulas.

Pharmacist: An individual who is fully licensed and approved by the relevant national authorities to practice pharmacy in Afghanistan.

Pharmacopoeia: A publication issued by an authorized national or international commission that specifies quality standards and other properties of pharmaceutical substances and dosage forms.

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.

Prescription only medicines: Medicines that can only be made available to the consumer through a written order signed by a duly qualified and registered medical prescriber and dispensed by a registered pharmacist.

Prescription: A written instruction signed by a registered and authorized health care practitioner to dispense specified medicines in specified quantities to a named patient.

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.

Product recall: A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product.

Program medicines: Medicines used in public health programs of MoPH, within the guidelines of the specific programs.

Psychotropic: Chemical compounds that cause abnormal changes in the functions of the nervous system and alter the physical, senses, and behavior in humans. Continuously using them will cause addiction, and stopping their use will cause adverse effects.

Public health: The prevention of disease, improving life, and promoting health through organized efforts of society related to populations/communities, as opposed to individuals.

Quality assurance: An integrated and complete system that includes the appropriate infrastructure, organizational structure, procedures, processes, resources, and systematic actions necessary to ensure adequate confidence that an organizational entity will satisfy the given requirements for pharmaceutical product quality.

Quality control: An integrated and complete process that documents all measures taken, including the setting of specifications, sampling, testing, and analytical clearance to ensure that raw materials, intermediates, packaging materials, and finished pharmaceutical products conform to established specifications for identity, strength, purity, and other characteristics.

Quality management: The degree of excellence of a service or a system in meeting the health needs of those most in need, at the lowest cost and within limits, directives, or regulations.

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

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

Therapeutic advantage: A significant improvement of efficacy or safety of one pharmaceutical product over another of the same therapeutic class seen in daily practice.

Therapeutic alliances: The cooperation of health workers with different qualifications in a private practice to increase accessibility to and quality of services provided.

Traditional medicine: A material or product of plant, animal, or mineral origin that is used in traditional practices to protect the health and to treat disease, whose effectiveness is proven by reliable traditional medicine sources.

BIBLIOGRAPHY

Hoen, E.T. 2009. *The Global Politics of Pharmaceutical Monopoly Power.* Diemen, the Netherlands: AMB Publishers, 44-58.

Islamic Republic of Afghanistan (IRA). 2008. *National Development Strategy. 1387-1391 (2008-2013).* http://www.undp.org.af/publications/KeyDocuments/ANDS_Full_Eng.pdf

Islamic Republic of Afghanistan, Ministry of Finance (IRA MF), Procurement Policy Unit. 2009. *The Rules of Procedure for Public Procurement*.

Islamic Republic of Afghanistan, Ministry of Public Health (IRA MPH). 2005. *Afghanistan National Health and Nutritional Policy* 2012-2020. Page 16. Para 3.3.3.

Islamic Republic of Afghanistan, Ministry of Public Health. 2005. *National Health Policy 2005-2009 and National Health Strategy* (NHS) *2005-2006.* http://moph.gov.af/Content/Media/Documents/Monitoring-Evaluation-Policy-Strategy2912201016288921.pdf)

Islamic Republic of Afghanistan, Ministry of Public Health (IRA MPH). 2010. *A Basic Package of Health Services for Afghanistan – 2010/1389*.revised edition.

Islamic Republic of Afghanistan, Ministry of Public Health. 2011. *Hospital Sector Strategy* (HSS).

Islamic Republic of Afghanistan, Ministry of Public Health (IRA MPH). 2011. *Strategic Plan for the Ministry of Health*: 2011-2015. http://www.gfmer.ch/SRH-Course-2012/country-coordinators/pdf/Ministry-Public-Health-Strategic-Plan-2011-2015-Afghanistan.pdf

World Health Organization (WHO) 2010. Donation medicine guidelines (revised document). Geneva. WHO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