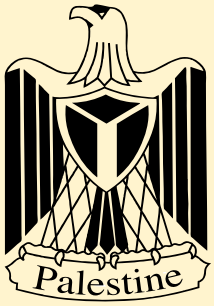
State of Palestine
Ministry of Health

National Pharmaceutical Policy

Pharmacy General Directorate

2013



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Preface

It is my pleasure to present the first edition of the National Pharmaceutical Policy that has come out as a result of the hard work exerted by a distinguished team of the General Directorate of Pharmacy with generous support of both the World Health Organization (WHO) and the French Development Agency (AFD).

In the Ministry of Health (MOH), we have always been working to adopt national health policies that promote provision of high-quality but cost-effective health care and services for all citizens while taking in consideration the limited financial resources. Since we are well-aware of the importance of medicines, we have adopted a national pharmaceutical policy to provide all citizens with safe, effective high-quality medicines. In order not to leave legal and legislative gaps related to medicines, we have put forward the broad lines of the national pharmaceutical policy to form guidelines for all the staff of the pharmacy sector so that they can bridge all the potential gaps and complete the required measures in order to achieve the objectives of the national pharmaceutical policy effectively and transparently.

The National Pharmaceutical Policy was completed and adopted in December 2012 and has become an integral part of the national health policy with the following components:

- Pharmaceutical Legislations,
- Selection Of essential Medicines,
- Pharmaceutical Quality Assurance,
- Pharmaceutical Logistics,
- Rational Use Of Medicines,
- Good Pharmacy Practice And Pharmaceutical Care,
- Pharmaceutical Economic Strategies,
- Human Resources,
- Pharmaceutical Research,
- Governance And Transparency,
- Technical Cooperation With Other Countries,
- Monitoring And Evaluation Of The National Pharmaceutical Policy.

We do hope that our work will achieve its desired benefits and add a new brick to the comprehensive health policy.

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National Pharmaceutical Policy

First: Introduction

The national pharmaceutical policy comprises an integral part of the health policy that should be included in the national pharmaceutical system. In this framework:

- The objectives of the national health policy must keep up with the general objectives of the health system. Applying this policy promotes the achievement of such objectives.
- The pharmaceutical status affects the methods of providing health services since they lose their credibility if there are inadequate supplies of high-quality medicines that match the adopted standards and specifications.
- Applying an effective national health policy promotes confidence in and benefiting from the provided health services.
- At the economic level, medicines costs are considered one of the most important health expenses that highlights the importance of financial affairs in the pharmaceutical field.

Second: Objectives

The main objectives of the national pharmaceutical policy are based on equity and sustainability in the pharmaceutical field. The general objectives of the national pharmaceutical policy are:

- Pharmaceutical Quality Assurance: To verify the quality, safety, and effectiveness of all medicines in addition to medical herbs and dietary supplements.
- Equitable provision and ability to afford costs of medicines.
- Rational use of medicines: To use medicines properly by health professionals and consumers taking in consideration costs and therapeutic effectiveness in addition to promote use of generic medicines.
- To support and promote the national pharmaceutical industries in order to develop their activities.

Third: Historical Background

- Prior to the setting up of the Palestinian National Authority (PNA), the pharmaceutical system was limited to quality control of medicines. Random samples of locally-produced medicines used to be tested by the pharmaceutical department of the occupation Civil Administration. Then, the quality control concept was reconsidered comprehensively to encourage local pharmaceutical factories to adopt self-control and abide to the international standards of good manufacturing practices (GMP).

- Following the establishment of the PNA, the General Directorate of Pharmacy in the Ministry of Health was created. By the end of 2007, the new structure of the General Directorate of Pharmacy was adopted. It consists of the following departments:
  1. Department of Pharmaceutical Policies,
  2. Department of Drug Control,
  3. Department of Dangerous Drugs,
  4. Department of Drug Quality,
  5. Department of Drug Registration,
  6. Department of Imports and Exports, and
  7. Department of Pharmaceutical Information.

Fourth: Components Of The National Pharmaceutical Policy

The national pharmaceutical policy consists of the following sections:

1. Pharmaceutical Legislations:

- Laws, regulations, and enforcement decisions are required to apply the national pharmaceutical policy and to achieve its objectives.
- The Ministry of Health is authorized to supervise the whole health and pharmaceutical system through its authorized departments.
- These legislations shall cover the following aspects:

- Practice and ethics of the pharmaceutical profession.
- The pharmaceutical affairs in all aspects including identification, manufacturing, control, importation, pricing, exportation, registration, promotion, marketing, distribution, dispensary, and after marketing control.
- Existing institutions concerned with medicine affairs and financing methods (General Directorate of Pharmacy, laboratories, and in general all institutions related to pharmaceutical affairs).
- Pharmaceutical Institutions that include pharmaceutical drugs factories, drugstores, public and private pharmacies.
- The criteria adopted in the state whose main objectives include the quality assurance of medicines "good manufacturing practice (GMP), good storage practice (GSP), good distribution practice (GDP), good laboratory practice (GLP), good pharmacy practice (GPP), and good clinical practice (GCP)" In this context, and where appropriate, the reference is the regulations issued by the World Health Organization (WHO).
- Categorization of narcotic substances, psychotropic substances and determine all

related aspects according to related international conventions.

- Definition of cosmetics preparations stores, raw materials, nutritional supplements and medical supplies stores in addition to the scientific offices.
- Identification of the supplies and medical devices, cosmetics, medicinal herbs and dietary supplements.
- In this framework, and following the adoption of this policy, the General Directorate of Pharmacy shall review all of the existing legislations to be updated when necessary and propose the non-existing ones.

2. Selection Of Essential Medicines

The list of essential medicines that meet the health needs of the population and that have been developed in consultation with the competent medical and pharmaceutical parties and in cooperation with experts from the World Health Organization is a basis for this national pharmaceutical policy.

The list of essential medicines was introduced in 2000 and is updated periodically by the Pharmacology and Therapeutics Committee. The Directorate of Pharmacy will continue this update with the help of the said Committee and publish it on the website of the Directorate. This update is carried out on the following bases:

- Evidence based medicine.
- The epidemiological situation in the country.
- The principle of cost effectiveness.

3. Quality Assurance Of Medicines:

The quality assurance of medicines that are traded in the public and private sectors is made through different systems makes up a network through which the Ministry of Health attempts to provide safe and effective drugs with high quality according to the approved standards. The quality assurance system includes the following pillars:

- Drug registration and approval of its factories,
- The adoption of quality assurance standards,
- Inspection and monitoring of pharmaceutical institutions, and
- Controlling medicines in pharmaceutical institutions.

The Ministry of Health is committed to supporting this national system with its needs, both human and financial.

3/1 Drug Registration And Approval Of Its Factories:

This is the technical and administrative process in which the General Directorate of Pharmacy identifies the components that ensure supplying the Palestinian citizen with safe, effective medicines with a quality that matches the standards approved nationally and internationally.

- In this regard, the political authority shall attempt to expand the supply sources of medicines as much as possible.
  The current situation (which mandates registration of medicines in the Palestinian National Authority unless they are registered in a neighboring country), although it has its pros, such as the study of these files from a neighboring country, hinders the process of diversification of supplies sources and reduces the potentials of competition and control of pharmaceutical expenditure.
- At the technical level, the Ministry of Health has to adopt its decisions on the following bases:

- Formation of a national committee for the registration of medicines and if necessary, setting up sub-committees or specialized committees under their auspices.
- Formation of a national committee to approve the domestic and overseas factories. During the preliminary phase, the actions of this committee are limited to ratify the local factories and study the critical situations of interest to foreign factories. In regard to foreign factories, the administration may adopt the documents issued by the competent authorities in the countries of origin in the framework of the authentication system of the World Health Organization

(WHO certification scheme).

- The Minister of Health or the one he authorizes shall ratify all the decisions. Upon ratification, the General Directorate of Pharmacy shall undertake to issue the official documents in this respect.
- All the fees of registration shall be delivered to the Ministry of Health for the aim of supporting and developing the General Directorate of Pharmacy.

3/2 Adoption Of Quality Assurance Standards:

The Ministry of Health is in charge of supporting and promoting the legislative and regulatory framework to ensure the quality of medicines and to ratify the national and international standards for medicines: GCP, GPP, GLP, GSP, GDP, GMP. In case of failure to provide for any part of these standards, the latest standards published by the World Health Organization in its most recent version shall be adopted.

3/3 Control And Inspection On Pharmaceutical Institutions:

Control and inspection make up the second pillar of the quality assurance of medicines. This process is based on the files available and approved standards in the country. In this period, the General Directorate of Pharmacy seeks to support this sector, especially at the coordination level between the central department and the relevant units at the provincial level.

3-4 Drugs Control In The Pharmaceutical Institutions:

Pro corner to the quality assurance of medicines is based on post-marketing control. In this context, the Palestinian National Authority is committed, under the guidance of the Ministry of Health, to strengthen the capacity of public health laboratory in charge of

monitoring medicines and health commodities.
The General Directorate of Pharmacy is also committed to develop an annual (or biannual) program to control the drugs at the levels of manufacturing and distribution. In addition, the Directorate shall study all the comments and complaints related to quality and to take all actions available in the framework of laws, regulations and decisions. The ministry shall also be committed to controlling counterfeit drugs and those traded illegally.

3/5 Note:

The state lacks a system to monitor the side effects of drug (pharmacovigilance). Although this system does not come automatically in the system of quality assurance of medicines and other needs, the Ministry of Health shall set up a system in this field, based initially on the establishment of a national commission or a national center to monitor the side effects of drugs and dependence on international aid available in this field, especially by WHO.

4. Drug Logistics:

- The responsibility of the continued availability of essential medicines in the country is a shared responsibility between the public and private sectors. The Palestinian National Authority has to continue the process of providing its affiliates with medicines via tenders taking into account the encouragements that are in place for the benefits of the local industry. The exercise of a good supply of pharmaceuticals and circulation in logistics cycle must be adhered to by both the private and public sectors.
- There should be emphasis on adherence to guidelines of drug donations and approved standards with familiarity of developments in this area at the level of the World Health Organization.
- All the brands in the Palestinian market, whether imported or locally manufactured, must be registered in the Palestinian Ministry of Health.
- Medicines are purchased according to the generic name of the drug in order to open competition among the largest number of bidders. Imported drugs must be authorized for circulation in the territories of the Palestinian National Authority and allowed to pass through the border crossings in legal ways.

5. Rational Use Of Medicines:

- In this respect, the pharmaceutical policy aims mainly to review the problems of wasteful, inappropriate prescription, excessive self-medication and treatment crossbar ailments that may not need medications. It also aims at reviewing the use of new highly-priced drugs, especially when there are safe effective generic drugs conforming to approved standards and at reasonable prices, and the rational use of medicine protects the health of citizens from the harmful health side effects of non-

rational use of medication.

- The General Directorate of Pharmacy shall create a committee charged with approving the media advertisements for medicines and develop standards for this process in collaboration with the UPPM and Trade Union specialized in this field. This Directorate must develop a strategy for:

- The collection, selection and dissemination of modern scientific information about modern scientific medicines from reliable sources. This process is carried out especially on the website of the Administration.
- Issuance and distribution of the national pharmaceutical policy document and a list of national essential medicines.
- Issuing a periodically-updated national drug formulary to form a guide when prescribing medications.
- Issuance of **Standard Treatment Guidelines** prepared by specialists for the treatment of common diseases.
- Activate the drugs and therapeutics committees in all hospitals.
- Organizing workshops, seminars and lectures on the rational use of drugs.
- Close cooperation and continuous coordination with specialists and professors from the faculties of medicine, pharmacy, professional associations and the media in the implementation of drug information program.
- Developing an integrated plan for information, education and communication with the public in the use of medication in accordance with the established scientific basis.
- Promoting mechanisms aimed at reducing demand and supply of narcotic medicines and psychotropic substances in the field of illegal trafficking, and participation in the fight against illegal trafficking in narcotic drugs and psychotropic substances and precursor chemicals.
- Providing recommendations to review the programs of medical and pharmaceutical sciences at universities and institutes, including subjects about essential medicines, and modern safe methods to rationalize prescribing and strengthen the curriculum of clinical pharmacy and therapeutics.

6 - Good Pharmacy Practice And Pharmaceutical Care:

Most of the work in the private sector includes the sale of the original packaging for drugs according to prescriptions from physicians of health clinics. Pharmacists play a limited advisory role. However, the activities of continuing education in private sector are limited to promote drugs only.

Policy objectives:

- To promote good pharmaceutical practices in order to ensure providing patients with the active form of the right medicine, specific dose, appropriate amount, clear instructions and packaging that keeps the drug's effectiveness.

- To practice, develop and sustain pharmaceutical care at hospitals, where continuing education activities shall be organized to encourage pharmacists in the public and private sectors to actively participate in educating patients about the use of medication.

7. Pharmaceutical Economic Strategies

7/1 The Role Of Government

The State has to provide a sufficient budget for the Ministry of Health in order to cover the medical needs in the field of essential medicines, serums, vaccines and medical disposables permanently. Furthermore, the role of government is to ensure that the poor are able to get the drugs they need.

7/2 Measures Designed To Promote Competition

The National Pharmaceutical Policy aims to encourage competition in order to get the medication at the lowest possible price, without overlooking quality.

Among the strategies that can be implemented to achieve this objective:

- Reviewing pricing instructions and making it more flexible. However, sales prices for the general public shall be fixed and united in all the territories of the country.
- State is committed to encouraging private competition by encouraging the manufacture and supply of generic drugs in order to control the cost of medicines.

The issue of drug pricing is based on the following basis:

- Pricing of medicines is the responsibility of the Ministry of Health,
- Pricing system takes into account the purchase power of the citizen,
- This system is based on prices in the reference countries and neighboring countries.

7/3 Medicine Funding

Medicine funding aims at making sure that there are allocations available to pay for the suppliers in order to ensure regular supply of drugs, medical devices and disposables.

Medicines in the public and private sectors will be funded from the following sources:

- The government's budget (Ministry of Health and the Military Medical Services),
- Private health insurance,
- Symbolic fees on prescription in public health institutions,
- Out of pocket expenditure,
- Non-governmental organizations.

7/4 Effectiveness And Economic Feasibility

The effectiveness and economic feasibility aim to provide essential medicines for all sectors at the lowest possible price and with minimal wastage. This will be achieved through the gradual and programmed implementation of the national pharmaceutical policy. The main thrust will be to reduce the costs and the high cost of treatment, through the following procedures:

- Promoting prevention programs, education, awareness, and environmental hygiene, especially in the field of medicine.
- Improving methods of estimating annual pharmaceutical requirements.
- Updating medication storage and distribution systems.
- Application of essential medicines lists and standard treatment protocols.
- Monitoring practices of medicine prescription.
- Updating the national drug formulary.
- Use registration as a way to make sure of the availability of medicines of high efficacy and low cost.
- Introduction and implementation of permission to allow generic substitution of brand drugs based on the findings of the required studies.
- Promoting a range of media activities on the rational use of medicines.

The annual pharmaceutical statistics shall constitute the main instrument for monitoring the evolution of the cost and use of medication.

8. Human Resources

The implementation of the pharmaceutical policy requires providing a number of professionals with higher specialization and expertise including physicians, pharmacists and other specialists in the field. The success of the implementation of the pharmaceutical policy depends on the availability of these cadres, which calls attention to their development. Consequently, the following objectives must by fulfilled:

- Determine the human resources need for all medicine facilities.
- Design short-and long-term plans in order to develop human resources for the provision of this need now or in the future.
- Prepare the necessary arrangements for training and continuing education for all employees in the field of medicine.
- Emphasis the role of universities and scientific institutes in rehabilitation of professional and technical manpower relative to the status of the pharmaceutical

sector and its needs in both quantity and quality.

- Benefit as much as possible from cooperation agreements between countries, regional and international scholarship programs, and training provided by the centers that cooperate with the World Health Organization.
- Participate in meetings, scientific conferences and specialized workshops on medicines inside and outside the country.

9. Field Research

The field research aims at the development of the pharmaceutical sector and study issues relating to the implementation of national pharmaceutical policy. In this area, work should be carried out in order to:

- Encourage technical cadres that are capable of leading the drug development process in the country.
- Encourage studies on drug stability across the pharmaceutical supply chain, and follow up the implementation of clinical studies and toxicity, bioequivalence and bioavailability within the legal framework prepared for this purpose.
- Develop and improve the available drugs.
- Propose and pass the act related to carry out clinical studies and drug experiments on human beings that take into account the ethics of scientific research and human rights in accordance with the rules established in this regard at the national and international levels.

10. Governance And Transparency:

The General Directorate of Pharmacy is committed in the context of the development of good governance practice (GGP) on the following basis:

- Develop criteria for workflow procedures for services.
- Develop a mechanism and code of conduct to deal with files, institutions and reviewers.
- Activate the issues related to the confidentiality of information
- Disclosure by administration officials and external experts accredited by the administration on any contradiction in interests (Conflict of Interest). This process is based on a permit renewed annually for each of these persons, “Declaration of Interest”
- In general, the Administration undertakes to put all the mechanisms that support transparency in its internal and external dealings. All of these data are posted on the website of the Department.

11. Technical cooperation with countries

The technical cooperation depends on contribution to the scientific knowledge and expertise generated in the other countries and benefit from them through agencies and international organizations in the fields of pharmaceuticals in the following areas:

- Drug information exchange.
- Issue quality certification of pharmaceutical products.
- Drugs Pharmacopeias.
- Training and development of manpower.
- Emergencies.

The Administration shall also seek to support the participation of the State of Palestine in the international meetings such as EMDRACAC and ICDRA through the regional office of the World Health Organization EMRO, and, in general, all the meetings related to drugs that the State of Palestine must participate in.

12. Monitoring and evaluation of national pharmaceutical policy

The General Directorate of Pharmacy undertakes to follow-up the achievement of the objectives of the national pharmaceutical policy with the material, moral and human support from the Ministry of Health. This is carried out through an annual report related to the achievement of the objectives of this policy which shall be submitted to the Minister and to the National Committee of the Pharmaceutical Policies. The General Administration also undertakes to establish mechanisms to renew the document every 5 years.