Hashemite Kingdom of Jordan

National Medicine Policy

2014

Designed By: JFDA\IT UNIT

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Preface

I am very proud and pleased to write the foreword of the second edition of the National Medicine Policy (NMP). This revised edition has focused on several policies that were not implemented from the first edition of the policy which was launched in 2002. This document was the result of the collective effort of representatives from various health sectors in public and private sector and civil society, with support of the World Health Organization and Medicine Transparency Alliance project (MeTA) in addition to solid consultation with relevant stakeholders in the pharmaceutical sector in order to ensure a coherent and multispectral platform for achieving the main goals of the national medicine policy.

The aim of this document is to define and unify the components of the national medicine policy. It also clarifies the factors affecting drug and pharmaceutical sectors in Jordan, both public and private. The objective, therefore, is to reach the best possible level of healthcare by providing medicines regulated according to the following criteria: safety, efficacy, quality and medical need and with affordable cost to the government and the patient.

This document includes the following key components: Selection of Essential Medicines; Affordability; Drug Financing; Supply System; Drug regulation; Rational Use of Medicine; Research and Development; Human Resource Development; Technical cooperation between countries, in addition to Monitoring and evaluation. The national medicine committee will develop a plan of action based on this comprehensive document which is funded by Medicine Transparency Alliance (MeTA).

In conclusion, I would like to express my sincere appreciation to all those who have contributed to the preparation of this important document and in particular the members of the NMP committee and MeTA Steering Committee, headed by Dr. Hayel Obeidat, and to WHO experts.

May God help us in our work towards the interest of this country under the leadership of His Majesty King Abdullah II Ibn Al Hussein.

Dr. Ali Hyasat

Minister of Health

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Table of Contents

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Introduction

This document provides a comprehensive framework for development of all components of the national pharmaceutical sector for the coming ten years including monitoring and periodic review, and sets appropriate goals for all pharmaceutical sectors, both public or private, taking into consideration all stages of dealing with the medicine like medicine procurement, manufacture, prescription, dispensing, and regulations, and it defines the national goals and objectives for the pharmaceutical sector, and set priorities.

The objectives of the policy are:

i. To ensure the availability of safe and effective medicines at the lowest possible prices for the population which meet approved standards, specifications, in accordance with genuine health needs and accompanied by a sufficient and reliable information to the prescriber and user;

ii. To ensure efficient and effective drug management in the public and private sectors;

iii. To promote the rational use of drugs by prescribers, dispensers and consumers;

iv. To promote the local pharmaceutical manufacturers technical, productive and marketing capacities for making it competitive for local and export markets;

v. To ensure that all drugs in the national drug distribution system are safe, efficacious, effective and of good quality;

vi. To strengthen administrative, legislative, and regulatory controls of the importation, manufacture, procurement, storage, distribution, supply, sale and use of drugs;

vii. To ensure a mechanism for the systemic collection and analysis of data on the use, medical need, performance (safety, efficacy and adverse drug reactions) and quality of medicines in the market;

viii. To promote operational research for the effective implementation of the National Drug Policy; and

ix. To enlist government commitment at all levels for the achievement of the goals and objectives of the National Drug Policy and to consider this policy as an integral part of the National Health Policy.

Key Components of the national medicine policy

1. Selection of Essential Medicines

The aim of essential medicines selection is to have a national list of medicines rationally chosen to satisfy the priority health care needs of the population and to ensure that those pharmaceutical products are available through the health care system. This goal will achieve through the development of essential medicines program which will include a list of essential medicines and standard treatment guidelines to encourage responsible use of these medicines.

In order to achieve this goal the followings actions should be taken into consideration:

i- The selection of medicines on the national medicine list will be based on the following criteria:

- The prevalence of particular diseases or medical procedures;
- Meet the priority health needs of population;
- Adequate data on efficacy and safety based on valid scientific evidence;
- Available in a form in which adequate quality, including bioavailability, can be assured; its stability under the anticipated conditions of storage and use must be established;
- Where two or more medicines appear to be similar in the above respects, the choice between them should be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price and availability.

ii. In cost comparisons between medicines, the following must be taken into consideration:

- The cost of total treatment, rather than the unit cost of the medicine;
- The cost/benefit ratio;
- Possible Improved patient adherence to treatment (compliance);
- Medicines and pharmaceutical form with high stability;
- Other factors, such as comparative pharmacokinetic properties.

iii. Fixed ratio combinations will only be selected if the following criteria are met:

- The clinical condition requires the use of more than one medicine;
- The combination has a proven advantage over single compounds administered separately in therapeutic effect, and safety;
- The cost of the combination is no more than the total cost of the individual products;
- Patient compliance is enhanced by the combination.

iii. Jordan Essential Medicines List will indicate the level of use of each item, based on the following classification:

- Primary health care centres
- Comprehensive health centres
- General hospitals
- Referral hospitals

iv. The essential medicines list should be adopted in all public sector institutions and should be promoted for use in the private sector.

v. Local pharmaceutical manufacturers should be encouraged to produce essential medicines.

vi. Jordan Essential Medicines List must be regularly updated, at least every two years because of advances made in drug therapy. The list will be distributed to all medical professionals in the country.

vii. The medicines should be registered by the JFDA, new registered medicines will only be introduced into the essential medicines list if they offer distinct advantages over existing essential medicines of the same therapeutic class and have favorable/risk ratios.

viii. The process of assessing and justification for the selection of medicines should be transparent and available to the public.

ix. There should be no conflict of interest among the members of the committees that select essential medicines.

2. Affordability

The objective of National Medicine Policy is to ensure that effective and safe medicines of good quality are accessible and affordable to the entire population. Jordan is facing the following challenges to achieve this goal:

- High prices of new essential medicines which their generics are not available in the market.
- Information imbalance, as the patient knows less than the prescriber or the dispenser about the efficacy, quality and appropriateness of the medicine and this can result in misleading advice and miscommunication, and ultimately inappropriate medicine use.
- Failure of competition either because of monopoly resulting from the exclusive rights, such as patents and trademarks, and when production is concentrated in a small number of suppliers.
- Some health services (such as treatment of infectious diseases and communicable diseases and some other diseases) benefit not only the person using them but others whose risk of illness is reduced. These third party or “spillover” benefits are externalities. Such health services, with

large public health benefits for society as a whole, cannot be left to the market and justify public investment.

- Bilateral trade agreements and International trade agreements and its impact on local production of medicines and the possibility of increasing the cost. The impact of the TRIPS Agreement on access to medicines should be carefully monitored and evaluated.
- Industry consolidation. The pharmaceutical industry is changing as the result of a wave of mergers, acquisitions and strategic alliances. The generic industry is also consolidating.

In order to increase affordability of medicines the following should be taken into consideration:

i. Medicine pricing policy:

- Review taxes and charges that are applied to medicines;
- Periodic review of the pricing guidelines (including the basket countries "External Reference Pricing"), according to the basis of a balanced and fair to the parties involved;
- Use the cost effectiveness studies for pricing medicines;
- There should be a feasibility study of the health and economic outcomes resulting from the application of the regressive mark-ups.

ii. Good procurement practices.

- Procure the most cost-effective medicines in the right quantities with the lowest possible total cost;
- Procurement should be effected in the largest possible quantities through the joint procurement department for the public sector in order to achieve economies of scale. There should be a feasibility study of the application of the direct purchase from pharmaceutical manufacturers to bid;
- Implement a unified procurement system for the purchase of medicines by all actors in the public sector.

iii. Medicine Security:

Medicine security is a broad concept that goes beyond providing sufficient quantity of essential medicines in a timely manner within a fair price to provide medicines which are continuously needed with quantities sufficient for a period of six months of national consumption, and also provide raw materials for the local pharmaceutical industry. As well as encouraging the industry to be expanded and developed and make it competitive. Medicine security policy can be achieved through:

- Develop a list of critical medicines that should be always available relevant to the health care setting and identify the strategic inventory for each item. And develop instructions for these critical medicines that should be permanently available;
- Securing strategic stockpile of critical medicines in the wholesalers or their manufacturers to ensure that the force of stock at pharmacies in the private sector and public sector;
- Amend the legislation to allow the availability and fast-tracking registration of critical medicines from local or international companies through giving priority to register items that are necessary and which has no alternative by speeding up the registration process in accordance with the requirements and the registration guidelines;
- Amendment of the legislation to allow parallel import when you need to achieve medicine security;
- Adopt a computerized supply system to improve efficiencies;
- In the absence of submitting registered medicines for tenders, offers of unregistered medicines from registered Pharmaceuticals companies can be submitted after providing documents which ensure the quality and efficacy of the medicine. A joint committee from the Food and Drug Administration and the Joint Procurement Department should be formed to issue instructions for these cases and for the required documents;
- Adoption of rational drug list (RDL) / Essential Medicine List (EML) by scientific name and therapeutic classification to be used for the purposes of procurement;
- Find ways for cooperation between the pharmaceutical industry and local government to achieve medicine security.

iv- Multi-source products:

To increase affordability for multi-source products the following strategy should be adopted:

- Encourage the use of generics / branded generic;
- The use of the scientific name in the bidding and prescribing medication in the public sector;
- Give priority and fast track registration for the first three generics.
- Unified prescription form in collaboration with the Medical Association (a prescription form should contain: Patient's full name and address, Prescriber's full name, address, telephone number, Date of issuance, Signature of prescriber' Drug name, dose, dosage form, amount' Directions for use and Refill instructions) ;
- Maintaining JFDA website that includes price information to enable physicians, pharmacists and consumers to assess the costs of treatment alternatives;
- Develop an educational strategy for drug prescriber, dispenser and consumers about the efficacy, quality, safety and price of generic medicine / generic brand name.

v- Single-source products

Policies contribute to the achievement of affordability for single-source products are the following:

- Develop a clear policy for voluntary licensing and compulsory licensing of medicines;
- Publish prices of medicines that are therapeutically equivalent (within the same therapeutic classes).

3. Drug Financing

The aim of drug financing is to ensure that funds are available to pay suppliers for the regular supply of needed medicines, medical devices and consumables. It includes commitment to measures to improve efficiency and reduce waste; increased government funding for priority diseases, and the poor and disadvantaged; and promotion of drug reimbursement as part of public and private health insurance schemes.

Financing the various provisions of the National Medicine Policy shall be the primary responsibility of government at all levels although the government is facing challenges like: Growing burden of chronic non - communicable diseases with a high cost and the emergence of new pattern of disease; Continuing increase in the medicines expenditure; The need for new medicines with high cost because of treatment failure with the earlier medicines; Steady population growth and the high proportion of elderly in the community; in addition to The role of government in protecting the needs of the poor and in achieving universal health coverage. Participation in the National Health Insurance Scheme by individuals, organizations and communities shall, however, be encouraged. In order to realize the objectives of the NMP, the Government shall ensure that:

i. Suitable financial provisions are made within the total health budget for sustainable implementation and monitoring of the policy.

ii. Adequate budgetary allocations are made for medicines, to ensure the availability of the necessary funding in the public sector to procure medicines and achieve credibility in payment to suppliers.

iii. Priority is given to the provision of adequate funds for medicines used in primary health care and the control of endemic diseases;

iv. The costs of the promotive and preventive aspects of the National Drug Policy like health information and education; human resources development and research are fully borne by government;

v. Government at all levels makes specific budgetary provisions to cover the cost of exemptions which shall apply to such categories of patients as poor, mentally retarded, children, and the elderly, etc.

vi. Develop a computerized supply system to support efficiency and reduce waste.

vii. Develop a computerized system to monitor the prescription and dispensing of medicines in the public sector.

viii. Develop standard treatment guidelines for the treatment of the common diseases in Jordan to reduce waste and contain medicine cost.

ix. Review health insurance systems in the public sector to achieve greater justice and introduce the concept of citizens' contribution in the health insurance contributions , and what is paid by the insured health as part of the cost of the medicine , taking into account the poverty line for a family as an indicator .

x. Issuing regulatory instructions to allow for rotation of the medicines between health institutions in the public and private sector.

4. Supply Systems

The aim of the supply of medicines is to ensure the safest and most cost-effective delivery of medicines, medical devices and consumables to the population through public, private and non-governmental organizations' supply system.

4.1 Medicines Supply

National medicine policy aims to provide the needs of citizens and provide essential medicines safe with efficiency and quality at affordable prices and distribute them equitably through:

i. Develop high efficiency medicine supply system, which ensures the flow of quality essential medicines on a regular basis at all times and in sufficient quantities to all health institutions.

ii. The present three separate supply systems of MOH, University Hospitals and the Royal Medical Services must gradually become integrated into one unified system, initially through applying the same standards and procedures to harmonize the supply systems.

iii. Issue a guide for medicine supply in the public sector include procedures, supply routes, inventory adjust and of good storage practices.

iv. Develop an effective national supply system for emergencies and disasters.

v. The private sector should have commitment to supply essential medicines and made them available to citizens in all parts of Jordan.

vi. The private sector should have commitment to supply medication as part of the national system with compliance of the rules of registration, licensing requirements, import, storage, and to support the public sector in the fight against counterfeit medicines.

vii. Training of the workers in the field of medicine supply at various levels in the areas of medicine supply, each according to his work and level.

4.2 Medicine Procurement

The purpose of medicines procurement is to obtain the required medicines at the lowest possible price without compromising quality and reliability of supplies. In order to achieve this goal the followings actions should be taken into consideration:

i. Medicines in the public sector will be procured through the Joint Procurement Department in order to keep prices low.

ii. Government shall be committed to good pharmaceutical procurement practices in the public sector; in which procurement at all levels shall be by open, competitive tender and shall be conducted in a transparent manner and be based on accurate quantification of drug requirements.

iii. Procurement of medicines shall be restricted to medicines registered in Jordan and accord priority to essential medicines to ensure that these are available in sufficient quantities to meet the needs of the population.

iv. Procurement in the public sector shall be by International Non-Proprietary Names (INN) or generic names only; Procurement and receipt procedures shall ensure that medicines supplied are of good quality.

v. To encourage local drug manufacture, preference shall be given to the purchase of locally manufactured medicines.

vii. A feasibility study should be conducted for long-term supply contracts through the Joint Procurement Department.

viii. Capacity building of staff should be improved through training of the workers in the field of medicine procurement.

4.3 Storage and Distribution of medicines

The objectives of medicine storage shall be to ensure stock security and the maintenance of the quality of medicines throughout their shelf life. The aim of distribution of medicines is to ensure that all supplies of medicines are distributed in a cost-effective way and equitably distributed to the different health care levels. In this regard the following measures shall be enforced:

i. Government shall ensure that suitably located, constructed and equipped storage facilities will be available at every level of the drug distribution system, in both public and private sectors and according to the requirements of good storage practices.

ii. The efficient and successful operation of a drug storage and distribution system requires the professional skills of pharmacists. Therefore, pharmacists shall be in charge of the drug stores operated by the public sector as well as in the private sector.

iii. Central Medical Stores and stores in both public and private health care facilities shall be properly managed to ensure that medicines do not expire or deteriorate on the shelf. However, any stock of expired or deteriorated drugs shall be officially destroyed within six months.

iv. Storage conditions for pharmaceutical products should be in compliance with the recommendations of the manufacturer. Recorded temperature monitoring data should be available for review. There should be defined intervals for checking temperature. The equipment used for monitoring should be checked at suitable predetermined intervals and the results of such checks should be recorded and retained.

v. Government at all levels shall ensure the establishment of central computerized inventory control systems in the central stores for effective drug management. Government shall encourage the computerization of private drug stores for effective inventory control.

vi. Adequate security shall be provided for storage areas, and, in particular, for narcotic drugs.

vii. Government shall establish inventory control systems, including computerization, in all hospital pharmacies and clinics for effective inventory control. These shall be linked to a central computerized inventory control system in the Central Medical Stores;

viii. A mechanism for joint inventory and distribution control must be established to allow redistribution of medicines between the public health care systems.

ix. Feasibility studies will be conducted to investigate a decentralized approach for hospital bulk consignment directly delivered by contracted local suppliers (wholesalers and importers) to major hospitals. The possibility will be investigated to organize either combined or direct deliveries to governorate medical stores or direct deliveries to the peripheral health facilities.

x. Medicine supply should adhere to good practices established in the field of the distribution of pharmaceuticals in the public and private sectors (Good distribution Practice).

xi. Training programmes for personnel in the field of medicine distribution and storage should be adopted.

4.4 Local Medicine Production

The policy aims to promote the domestic industry's technical, productive and marketing capacities for making it competitive for local and export markets, a basic aim in developing local medicine production is to enable local supplies to be developed which serve both the national public health interest and the national economy. In order to achieve the target of greater reliance on local drug production, the following steps shall be taken:

i. Encourage the domestic industry's research and development work toward the production and marketing of new and improved products.

ii. Ensure high quality productions of domestic medicine industry in accordance with approved good manufacturing practice.

iii. Encourage the establishment of plants for the production of basic raw materials.

iv. Encourage patronage of local drug manufacturers in government tenders.

v. Take action to increase the competitiveness of the local pharmaceutical industry

vi. The government should encourage local industries for the production of essential medicines to help achieve self-sufficiency in essential medicines.

vii. Pharmaceutical manufacturers shall be encouraged to maximize the use of their installed production capacity for export purposes.

viii. Training of technical staff in domestic medicine industry, both internally and externally to acquire the latest technical skills that will enable them to keep pace with the constant evolution in the pharmaceutical industry.

5. Drug regulation

Jordan Food and Drug Administration is the regulatory authority that develops and implements legislation and regulations on pharmaceutical in order to ensure the quality, safety and efficacy of medicines and the accuracy of information. And to ensure that medicines are produced, imported, exported, distributed, supplied, promoted and clinical trials of medicines conducted according to specific criteria.

5.1 Challenges

• Limited qualified and trained human resources;

• Technological development and globalization of the pharmaceutical market;

• The difficulty of obtaining accurate and reliable information;

• Limited participation of health civil society organizations in the development of drug policies and their implementation;

• Counterfeit medicines.

5.2 Legislative and Regulatory Framework

1. Pharmaceutical Legislation

Legislation is the instrument by which the implementation of a drug policy is given a legal basis by statutorily defining the various strategies for achieving the objectives of the policy. It also defines the qualifications, duties, privileges, and obligations of individuals, organizations, institutions, and other bodies concerned with the implementation of the various strategies of the policy, and provides for sanctions in the event of violations. For the effective implementation of legislation, there is need to review and update the relevant laws regularly, in consultation with relevant stakeholders, in order to achieve the desired objectives. Jordan Food and Drug Administration will review legislation and regulations in order to support the objectives of the NDP. The followings actions should be taken into consideration:

i. Issue guidelines for fast-track registration for medicines which are of distinct advantage over those existing medicines.

ii. Establishment of system for monitoring of adverse drug reactions and recall of medicines.

iii. Issue guidelines for safe disposal of expired and waste pharmaceuticals.

iv. Administration of drug promotion control including penalties and appeal procedures.

v. Revision of the guidelines for drug classification according to prescribing (prescription-only items, repeat prescription items, over-the-counter items, narcotics and psychotropic substances) and update the lists and disseminate it in order to monitor the prescription and dispensing of these items.

vi. Updating pharmaceutical legislation relating to: registration, inspection, pricing, importation, exportation, supply, storage, distribution, prescription, dispensing, promotion and advertising, and post-marketing surveillance according to the global developments and the need for it.

vii. Updating legislation related to the regulating of medical equipment and disposables, cosmetics and herbal medicines according to international developments and the need for it.

viii. Development of legislation to regulate the registration, pricing and inspection of veterinary medicines through the Jordan Food and Drug Administration.

ix. Development of legislation for parallel importation and compulsory licensing in accordance with Trade-Related Intellectual Property Rights (TRIPS)

x. Development of guidelines to achieve medicines security (availability of quality assured essential medicines).

2. Transparency and Governance

i. Preparation of transparent mechanisms to deal with the institutions and the public in which all the required steps, procedures, paperwork, or other requirements are presented clearly

ii. Publishing of the draft legislation on the website before approval for feedback from partners.

iii. Announcement of results of the evaluation of the client services provided by the Jordan Food and Drug Administration periodically.

iv. Publishing the decisions issued by the Jordan Food and Drug Administration which is related to medicines on the Website.

v. Development of the website of the Jordan Food and Drug Administration in a way that ensures easy access to information for the public, private sector and Civil Society Organizations.

vi. Publishing the leaflets for the registered medicines on the website of the Jordan Food and Drug Administration.

vii. Development of procedures to ensure the confidentiality of information and documents which should be safeguarded.

viii. Enhance the efficiency and effectiveness of the Jordan Food and Drug Administration through the creation / activate a mechanism to enable partners to follow the medicine registration file electronically and to follow the laboratory test results.

ix. Formation of a committee comprising all institutions concerned with medicine on the managerial and executive levels to activate the dialogue and the creation of integration between these institutions.

x. Sharing information about medicines and its availability in the manufacturers and wholesalers between the Food and Drug Administration and the Joint Procurement Department and the Ministry of Health, through electronic connectivity.

xi. Strengthening the role of civil society through the involvement of experts from health civil society in the technical committees in the Food and Drug Administration.

xii. Declaration by the experts participating in the Committees of any conflict of interest and assess potential conflicts of interest.

xiii. Computerization of information about pharmaceutical institutions and licenses pharmacists in the Directorate of professions and licensing / Ministry of Health and link it with the Food and Drug Administration and update it constantly.

xiv. Enhancement the efficiency of the inspection of pharmaceutical institutions and study the possibility of unification of the supervisory authority.

xv. Revision of the guidelines of pharmaceutical licensing in addition to the electronically publishing of licenses decisions and institutions sites.

xvi. Ensure periodic and regular publication and wide dissemination of the list of registered drugs.

3. Quality Assurance

The aim of quality assurance of pharmaceutical products is to ensure that the medicine provided to the patient is safe, efficacious and of good quality. The process of quality assurance begins from the manufacturer and continues to the point of administration of the drug to the patient. Compliance with Good Manufacturing Practices (GMP) is an important component of quality assurance.

Therefore, government shall take appropriate action to ensure that regulatory authorities are strengthened and empowered to monitor and enforce effective compliance with quality assurance provisions by manufacturers of imported and locally produced drugs to ensure that patients and consumers receive only safe, efficacious and good quality drugs. This can be achieved through:

i. Strengthening of the legislative and regulatory framework to ensure the quality of medicines based on national and global standards for medicines.

ii. Capacity building of the Food and Drug Administration to reach the stage of ability to evaluate all aspects of a registration dossier.

iii. Good Manufacturing Practices [GMP] shall continue to be monitored and enforced in all drug manufacturing outfits in the country and summary reports of problems identified during inspection of pharmaceutical manufacturers should be disseminated.

iv. Development of inspection procedures through twinning with countries with established best practice protocols.

v. Development of the procedures and mechanisms of action for analysis medicines in the Drug Quality Control Laboratory in order to become an international reference laboratory.

vi. Capacity building of Drug Quality Control Laboratory to enable analysis of biotechnology medicines.

vii. Development of mechanism of action for the sampling process for analysis purposes in the Food and Drug Administration.

viii. Awareness campaigns for consumers on the subject of counterfeit medicines in cooperation with the relevant authorities.

4. Medicine Safety and Pharmacovigilance

Since no active drug is entirely free from adverse reactions, the introduction of an adverse drug reaction reporting system is an essential component of a national healthcare delivery system, government shall, therefore, encourage the development of adequately equipped pharmacovigilance units nation-wide, to collect, evaluate and disseminate relevant information on adverse drug reactions and poisoning. All medicines shall be regularly monitored with respect to their efficacy, safety, quality as well as adverse reactions to evaluate the need to change the conditions of their continuing registration or withdrawal from the market. The following activities should be adopted to monitor medicine safety:

i. Increasing awareness of health service providers and the consumer to the importance of monitoring side effects and procedures and reporting issues related to the quality, safety and efficacy of the medicines.

ii. Development and creating a database in the pharmacovigilance unit available to all concerned parties to monitor the side effects of medicines and problems related to its use and support pharmacovigilance unit with qualified staff.

iii. Development of regular summary reports of data on medicines safety and regulatory actions undertaken and disseminate it.

iv. Activating the role of the Ministry of Health and the relevant authorities in monitoring prescribing practices.

5. Medicine efficacy and clinical trials

i. Strengthening the legislative and monitoring environment to attract conducting clinical studies in Jordan.

ii. Requesting conducting clinical studies for certain medicines by the Food and Drug Administration within specific basis.

6. Pharmaceutical information and drug promotion

i. Development of drug promotion control legislation to include penalties for breaching the guidelines.

ii. Development of a regulatory mechanism for the implementation of drug promotion control guidelines.

iii. Capacity building of the National Center for Pharmaceutical Information to provide objective drug information to physicians , pharmacists and patients , and through cooperation with the Drug Directorate and media.

7. Herbal and Other Traditional Remedies

Herbal and traditional medicines are widely used in the country. Many of the drugs used in modern medicine today originate from plants and there is no doubt that these herbal and traditional medicines can have adverse effect, therefore the following should be taking into consideration:

i. Rational use of herbal medicines;

ii. Investigation of traditional medicines, particularly herbal medicines for efficacy, safety, and quality.

iii. Encouragement of the development of a “Code of Practice” by herbal medicine practitioners;

iv. Regulation and control of advertisements of traditional medicine and practices by the government;

8. Controls of Veterinary Drugs

The objective of controlling veterinary drugs is to ensure the safe and rational distribution, storage, prescribing, dispensing and use of veterinary drug products. The uncontrolled administration of veterinary drugs, particularly the use of antibiotics and hormones in animals used for food leads to the presence of residues of these drugs in meat and meat products. It also leads to the development of resistant strains of micro-organisms.

Consequently, government shall enforce the following measures:

i. The essential drugs concept shall equally apply to the procurement, distribution, supply and utilization of veterinary drugs. Government shall setup a committee comprising competent persons in the field of veterinary medicine, agriculture and pharmacy to compile a list of Essential Veterinary Drugs, Standard Treatment Guidelines and a Veterinary Drug Formulary to be adopted for use throughout the country;

ii. The utilization of veterinary drugs shall comply with ethical veterinary practices, and government shall ensure the effective monitoring of drug utilization in this sector;

iii. Generic prescribing shall be adopted by appropriately authorized and registered prescribers;

iv. The sale of veterinary drugs shall be undertaken by pharmacists and any other persons authorized or licensed by the Ministry Of Health.

6. Rational Use of Medicine

The rational use of medicines means that patients 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 their community.

i. Rational use of medicine is an essential element of a National Medicine Policy seeks to avoid the all-too-frequent problems of under- and over-prescription, inappropriate prescription, and the use of new, expensive drugs when equally effective, well tried, safe and cheaper alternatives are available. The importance of promoting rational use of medicine includes:

- Enhances the quality of health care with lowest cost of treatment;
- Ensures the use of the medicine only when it's needed to avoid the undesirable medical and economic consequences;
- Helps to increase awareness about the medication and ensure patient adherence to treatment;
- Raises the confidence of the public health care system;
- Reduces wastage of resources and therefore medicines costs and will free resources to purchase essential medicines in other needed areas.

ii. The challenges that are facing Jordan to implement rational use of medicine policies include:

- The impact of social and cultural beliefs on the rational use of the medicine;
- Conflicts of interest and the personal interests that affect the right choice;
- Lack of access to regular up-to-date independent medicine information and health workers and consumers are almost entirely dependent on commercial sources of information;
- Inappropriate promotion of medicines;
- Dispensing of medication without a prescription;
- Prescribing medicines with brand names instead of generic names;
- Lack of medicine utilization studies and prescription reviews.

6.1 Strategies to implement rational use of medicines

Concerted efforts shall be made by government at all levels to promote rational drug use through the following strategies:

1. Educational strategies

The objective is to ensure that all health personnel involved in the diagnosis, prescription and dispensing of drugs, as well as consumers, receive adequate theoretical and practical training in rational drug use. It will, therefore, be necessary to take the following initiatives:

A. Basic training of health professionals

- The principles of the rational use of medicine, essential medicines concept, critical appraisal skills and good communication skills should be included in the curriculum of all health workers;
- Good prescribing practice skills should be included in the curriculum of medical students;
- Good dispensing practice and good pharmacy practice should be included in the curriculum of pharmacy students.

B. In-service training of health workers

- Continuous medical education and training of physicians on standard treatment guidelines through lectures, conferences, workshops and scientific seminars funded by the public health sector to ensure access to independent and non - biased medicines information;
- Development of instructions for monitoring of prescribing practice and linked it to their incentives;
- Creation of an education and continuous training system for health providers so as to raise the efficiency of staff through training courses and workshops on the concept of the rational use of medicines, essential medicines concept and good prescribing practice based on standard treatment guidelines;
- Expanding the umbrella of the Jordanian Medical Council to include the establishment of the Jordanian Pharmaceutical Council to be responsible for continuous pharmaceutical education and to prepare the instructions for the classification of pharmacists;
- Issuing periodic bulletins about the rational use of the medicine by the Food and Drug Administration for health care providers in collaboration with the health professional syndicates;
- Raising awareness of the role of the Food and Drug Administration in insuring quality of medicines by holding workshops for health care providers.

C. Public education

- The inclusion of the rational use of the medicines concept for teachers and students in the curriculum of the schools;
- Consumers education through health programs in the media in the fields of rational use of medicine;
- Patients education by health care providers, about the importance of using medicines and how to use them, and the importance of compliance to the treatment;
- Preparation of educational brochures convenient for the patients, taking into account cultural diversity and the impact of social factors;
- Public education about the basic concepts related to medication to enable them to take appropriate decisions when there is a need for self- medication;
- Civil society organizations involvement in the health plans and medicine education programs;
- Preparation of educational programs with clear measurable objectives;
- Raising awareness of the role of the Food and Drug Administration in in insuring quality of medicines through various means to the public.

D. medicine information

The objective of medicine information is to ensure that all medicine prescribers, dispensers and users access to objective unbiased, scientifically validated medicine information to promote rational prescribing, dispensing and use. In this respect, therefore, the following measures shall be taken:

- Creation of a national center for pharmaceutical information in the Food and Drug Administration which will provide comprehensive medicine information services (brochures, scientific articles and publications), either directly or through media channels;
- Creation of a national center for toxicity to be a reference on the problems of drug poisoning;
- Provision of adequate scientific medicines information to the physicians, pharmacists and nurses through updating national drug formulary which contains information about indications, dosage and method of use, contraindications, side effects, and drug interactions;
- Provision of information about registered medicines through the website of the Food and Drug Administration in addition to publish national drug formulary and rational drug lists on its website.

2. Administrative policies

A. Standard treatment guidelines and rational medicine lists

- Issuing national standard treatment guidelines of the most common diseases by the Higher Health Council for each level of health care;
- Selection of medicines in rational drug list should be based on scientific evidence;
- Development of standard operating procedures to choose the members of the selection committees of rational drugs;
- The National Center for Pharmaceutical Information should provide scientific information about the medicines that are submitted to rational drug list;
- The rational drug list should be available and there should be instructions to prescribe it by the physician as possible;
- Development of procedures to encourage adherence to standard treatment guidelines and rational drug list.

B. Pharmacy and therapeutics committees

Pharmacy and Therapeutics Committees are institutionalized mechanisms for promoting, implementing and monitoring the concept of rational drug use in healthcare institutions. Therefore, the following measures shall be taken:

- Pharmacy and Therapeutics Committees (PTCs) shall be established at each public hospital with clear duties and term of references;
- Membership of such committees shall comprise representatives of the pharmaceutical, nursing, medical, and administrative services of the institution;
- A PTC shall, among other duties, be responsible for:
  - The selection of drugs for use in the institution, based on the National Essential Drug List/ Rational Drug List;
  - The accurate estimation of pharmaceutical requirements for the hospital;
  - Monitoring of the use of therapeutic guidelines and overall drug utilization;
  - Monitoring of the rational use of drugs in the institution.

C. Prescribing

The objective is to ensure that drugs are prescribed rationally. Consequently,

- Prescribing medicine by generic name or international nonproprietary name (INN);
- Classification of rational drug list by according to prescribing classification into three groups:
  - Unrestricted Medicines;

- Restricted Medicines (prescribed by specialized physicians)
- Authorized Medicines (Medicines require prior approval);

- To develop a system of electronic prescribing of the medicine and to build an information database and create an effective system to monitor prescriptions in order to support the rational use of medicine;
- Transformational system suitable for patients to allow the time necessary for the physician to do his duties;
- Development of computerized mechanisms to prevent duplication of treatment;
- Development of instructions of good prescribing practice specifying the information to be provided related to prescriptions, patient and treatment, including the dosage form, quantity, duration, signature, and replacement;
- Development of policies to address the problems of antimicrobial resistance and misuse of antimicrobials, using WHO and other international best practice guidelines;
- Separation the task of dispensing from the prescription.

D. Dispensing of medicines

The objective of rational dispensing shall be to ensure that patients receive adequate information on the use of dispensed drugs in order to derive the desired benefits to them. In this regard the following shall be put in place:

- The minimum information requirement on the label of a dispensed medicine shall be the following: Name of patient; Generic name of dispensed drug; Strength of the drug; Dosage instruction in symbols or words as may be appropriate; Duration of treatment; Date of dispensing; and the name of the institution where the drug was dispensed;
- The patient shall be counselled on the use of dispensed drugs, in a conducive environment suitable for effective communication;
- To investigate an appropriate scheme of patient copayments that promotes responsible use of medicines but does not limit access to necessary medicines;
- Issuing of instructions to monitor and record the prescriptions in public pharmacies.

3. Regulatory Policy

A. Medicine registration and monitoring of side effects

- Measures should be taken to achieve transparency, including the preparation and distribution of lists of registered medicines classified by dispensing method;
- Implementation of strategies and mechanisms to monitor the side effects of medicines.

B. Medicine Promotion

- The adoption of regulatory mechanisms for the purposes of monitoring and evaluating compliance with the medicine promotion control guidelines;
- Revision of the medicine promotion control guidelines and include appropriate penalties stemming from the violation of these instructions;
- Raising awareness of health care providers and the public about the impact of the medicine promotion by the pharmaceutical companies on the rational use of medicines.

C. Self-Medication

Self-medication is especially useful in any situation where access to health care facilities is limited. It can offer the advantage of providing quick and effective relief that does not require medical attention, thereby relieving pressure on medical personnel and freeing them to devote more time to serious problems. However, it could lead to inappropriate use of drugs, delay of proper diagnosis and the delivery of effective treatment. It could also lead to drug misuse and abuse. In order to obtain the benefits of self-medication while avoiding its risks, the following steps shall be taken:

- A list of medicines that can be sold without prescription and used for the short-term relief of symptoms, without prior medical consultation and precise diagnosis, shall be drawn up and published by JFDA;
- The list shall be reviewed from time to time in the light of experience and available new information;
- Information on, and the labelling and promotion of drugs, meant for self-medication, shall conform to laws and regulations set out for such categories of drugs;
- Health education to the public on appropriate self-medication shall be provided through different communication methods.

7. Research and Development

The aim of Research and Development [R&D] is to promote, encourage and support ethical, scientific and field research in the pharmaceutical sector and facilitate the effective implementation of the National Drug Policy to meet the health care needs of the country.

i. Pharmaceutical research aims to improve and develop new medicines, which include formulas, pharmaceutical production processes, new clinical trials for medicines and vaccines. This can be achieved through:

- Encouraging the manufacture of biotechnology medicines with high quality and appropriate cost in Jordan;
- Encourage technical staff of leading the process of medicine development;
- Encourage stability studies for the pharmaceuticals and follow up the implementation of clinical studies, bioequivalence studies and bioavailability studies within the legal framework prepared for this purpose;
- Documenting and reducing adverse drug reactions.

ii. Field research is necessary for the successful implementation of the National Medicine Policy. Its aim is to improve understanding of the factors influencing the use of medication and identify the best methods of selecting, procuring, distributing and using drugs rationally. Its application shall lead to practical and cost-effective measures which would inform managerial, educational and regulatory interventions to improve access to and the use of drugs. Research will focus particularly on the following areas:

- Identifying the impact of the National Drug Policy and its components on the national health system and health service delivery;
- Drug utilization at different levels of health care facilities;
- The economics of drug supplies;
- Social and cultural aspects of drug use, such as self-medication, acceptability and attitudes of drug consumers, etc.

8. Human Resource Development

The aim of human resources development is to develop highly qualified and experienced professionals in the public and private sector including medical doctors and pharmacists and paramedical staff to support the effective implementation of national medicine policy.

Well-trained and experienced professional, managerial, technical and other personnel are necessary for planning, organizing, and implementing the National Medicine Policy. Government shall, therefore, take the following actions:

i. Ensure constant review of pharmacy and medical curricula, in cooperation with the relevant professional regulatory bodies to reflect the needs of drug policy implementation;

ii. Develop in-service training programmes to address on-the-job requirements in the implementation of the policy;

iii. Revision the Curricula of institutional training programs to produce suitably qualified and knowledgeable health personnel

iv. Career development, including continuing education in line with new scientific and technological developments

v. Institutional and in-service training of various categories of professional, technical, managerial and administrative staff required for the national health care system, including specific needs as: the principles of national medicine policy and the concept of essential medicines, rational use of medicines, effective prescribing and treatment guidelines, registration and regulation of the medicines, medicine supply management, hospital pharmacy administration, management information systems, pharmacoepidemiology, pharmacoeconomics, principles of pharmaceutical care and clinical pharmacy.

vi. Development of criteria for evaluating the performance of various categories of professional, technical, managerial and administrative staff required for the national health care system so that they are directly linked to clear indicators which measure the employee's ability and performance.

vii. Strengthening cooperation with other regional and international regulatory authorities, research institutes, local pharmaceutical industry and relevant international agencies such as the World Health Organization for the purpose of enhancing human resources development for the efficient implementation of the National Drug Policy.

9. Technical cooperation between countries

Cooperation between countries can be advantageous in combating the influx of sub-standard and counterfeit drugs into importing countries, and thereby help to reduce substantially illicit drug trafficking, also can contribute and benefit from experiences and scientific knowledge gained in other countries in the region and through international agencies and organizations in the field of pharmaceuticals. Such cooperation shall be achieved through:

i. The establishment and maintenance of appropriate channels of communication and exchange of information between drug regulatory and law enforcement authorities;

ii. Promoting the training of personnel and human resource development;

iii. Exchange of information on substandard and counterfeit drugs in international commerce;

iv. Liaising with the International Narcotics Control Board and governments of other countries to limit the importation and use of narcotic drugs and psychotropic substances to medical and scientific purposes only.

v. Twinning with other international regulatory agencies with established capacities in laboratory quality control.

vi. Sharing information on registration dossiers, information on quality of products assessed and pricing information.

10. Monitoring and evaluation

The aim of monitoring and evaluation is to ensure the successful implementation of national medicine policy by establishing monitoring and evaluation mechanisms under the policy. This can be achieved through:

i. The setting up of a National Medicine Policy Monitoring and Evaluation Unit in the JFDA to measure progress in the implementation of the policy and to run a national evaluation scheme.

ii. Formation of a national team to monitor and evaluate national medicine policy.

iii. Develop indicators to measure progress toward the goals must be used and make comparisons over time, these indicators should be specific, measurable, achievable, realistic and time-bound, and must allocate the necessary budget for the implementation of these goals.