Support to Develop a Draft Law Establishing the Liberian Medicines and Health Products Regulatory Authority

Monrovia, Liberia
February 2-6, 2009

Trip Report

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**About USP DQI**

The Drug Quality and Information (DQI) Program is implemented by the United States Pharmacopeia (USP) and funded by the U.S. Agency for International Development (USAID) (Cooperative Agreement HRN-A-00-00-00017-00). The DQI Program provides technical leadership to more than 30 developing countries to strengthen their drug quality assurance programs, ensure the quality of medicines and promote public health. DQI helps build local, national and regional capacity to improve the standards of drug manufacturing and distribution, reduce the impact of infectious diseases, mitigate the effects of the HIV/AIDS epidemic, and advance the appropriate use of medicines. This document does not necessarily represent the views or opinions of USAID. It may be reproduced if credit is given to USP DQI.

**Abstract**

The DQI Program was selected by USAID/President’s Malarial Initiative (PMI) to assist Liberia in ensuring the quality of antimalarial medicines. In November 2008, a DQI team conducted an assessment of Liberia’s capacities in quality assurance and quality control and found that Liberia does not have the functional systems to assure or control the quality of medicines. This was mainly due to the absence of a National Drug Policy, the lack of drug regulations, and the lack of quality control capacity. Aware of the situation in the pharmaceutical sector, the Minister of Health (MOH) created the Liberian Medicines Regulatory Committee (LMRC) to draft legislation to create a drug regulatory authority and regulate the pharmaceutical sector in Liberia. After discussion with the USAID/Liberia Mission, the World Health Organization and country partners, it was decided DQI should first focus attention first on assisting the LMRC to review, draft, and finalize the drug legislation.

During this trip, DQI worked with the LMRC, USAID, the Pharmacy Board of Liberia, and the country’s Malaria Control Program to finalize drug legislation for submission to the Liberian Parliament for approval.

**Recommended Citation**


**Key Words**

LMRC, LMHRA, Legislation, Good Regulatory Practices, USP, DQI, Board of Pharmacy of Liberia, drug regulations
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DQI team would like to express sincere appreciation to all the participants in the LMRC workshop for the fruitful discussions during the drafting of the legislation. In addition, particular thanks go to Dr. C. Bright Parker for chairing the meetings, to Chief Pharmacist, Rev. Tyee, for helping DQI with logistics, and to the Chairman of the Board of Pharmacy of Liberia, Mr B. Johnson, for his inputs.

The authors wish to express their appreciation to the DQI administrative staff and editors for their assistance with logistical arrangements and for editing the trip report.

Finally, the authors would like to thank Mr. Kaa Williams for his great support to the DQI team, his valuable contribution to the workshop and his help with the trip preparation. Mr. Kaa participated vigorously in the discussions about the drug legislation, representing public interest in the legislation, and reminding the group of how government institutions work in Liberia. The DQI team would also like to express their sincere gratitude to USAID PMI Advisor Dr. Kassahun Belay for his support and assistance during this trip.

Last, the DQI team would like to express its gratitude to DQI CTO Mr. Anthony Boni and Ms. Veerle Coignez at USAID Washington for their guidance and helpful insights throughout the preparation stages of the workshop.
**ACRONYMS**

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<thead>
<tr>
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<th>Full Form</th>
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<tbody>
<tr>
<td>CTO</td>
<td>Cognizant Technical Officer</td>
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<td>DQ</td>
<td>Drug Quality</td>
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<td>DQI</td>
<td>Drug Quality and Information Program</td>
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<tr>
<td>GFATM</td>
<td>Global Fund to Fight AIDS, Tuberculosis and Malaria</td>
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<td>LMRC</td>
<td>Liberian Medicines Regulatory Committee</td>
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<td>LMRA</td>
<td>Liberian Medicines Regulatory Authority</td>
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<td>LMHRA</td>
<td>Liberian Medicines and Health Products Regulatory Authority</td>
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<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>NDQCL</td>
<td>National Drug Quality Control Laboratory</td>
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<td>NDS</td>
<td>National Drug Supply</td>
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<td>PMI</td>
<td>President’s Malaria Initiative</td>
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<td>QA</td>
<td>Quality Assurance</td>
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<td>QC</td>
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<td>United States Pharmacopeia</td>
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<td>WHO</td>
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BACKGROUND

The DQI Program conducted an assessment of medicines quality control and quality assurance (QA/QC) capabilities of the Republic of Liberia in November 2008. Based on that assessment, DQI concluded that the first priority in building a functioning quality assurance system was to draft legislation establishing a new medicines regulatory authority.

From February 1-7, 2009, a DQI team traveled to Monrovia, to support the Liberian Medicines Regulatory Committee (LMRC) in finalizing the draft regulatory text to be presented to the Liberian Legislature. The DQI team consisted of Dr. Abdelkrim Smine, DQI consultant; Dr. Eshetu Wondemagegnehu, DQI consultant; and Ms. Veerle Coignez, U. S. Agency for International Development (USAID) consultant.

Purpose of Trip

USP DQI staff traveled to Monrovia, Liberia, to:

1. Meet with the Liberian Medicines Regulatory Authority committee, Pharmacy Board of Liberia, Ministry of Health, USAID/Liberia Mission and Malaria Control Program to discuss the drug quality control capabilities of Liberia and how DQI can strengthen the quality control lab of the Ministry of Health.

2. Work with Liberian program partners and USAID to finalize the drug legislation establishing the Liberian Medicines Regulatory Authority.

3. Debrief USAID about the details of the draft legislation and discuss future activities DQI can conduct to strengthen the country’s quality control and medicines regulatory capacities.

4. Meet and update the Ministry of Health about DQI activities.

Trip Schedule

On the first day, the DQI team met with Dr. C. Bright Parker and the relevant LMRC members to discuss the establishment of a National Drug Quality Control Laboratory (NDQCL). The following days were dedicated to negotiating the draft legislative text. On the last day, the DQI team visited two potential sites for a temporary NDQCL and debriefed the USAID Mission and the Ministry of Health.

Source of Funding

This activity was funded by the USAID Mission in Liberia, PMI Program.
OVERVIEW OF ACTIVITIES

I. The Medicines Quality Control In Liberia

1. DQI convinced Dr. Bright Parker and her team to limit activity in the current facility to basic testing, given that the building is neither safe nor fit to house sophisticated and expensive equipment. DQI recommended that the LMRC even find a better temporary lab facility while awaiting the construction of the new NDQCL.

2. DQI arranged for one staff member from the National Drug Services (NDS - Mr. Jolo Mulbah) to attend the Minilab® training being conducted by DQI in Ghana during the second week of February 2009. After being trained, Mr. Mulbah will begin carrying out Minilab® testing on selected essential medicines. DQI will provide new reference standards for the Minilabs® (which the Laboratory received from UNDP).

3. The DQI team visited two potential sites to be used by LMHRA as a temporary facility while the new national quality control laboratory is being built. The first site visited was at the School of Pharmacy, but the building was still under construction and it was impossible for the team to determine the suitability of this site for use as a quality control lab. The second site is a laboratory used by the Ministry of Health (MOH). This facility is suitable for use as a temporary quality control laboratory, once minor work is done to fix the roof and secure a small chemical storage room.

II. The Draft Act

1. The DQI team, LMRC, Board of Pharmacy of Liberia, National Malaria Control Program, and National Drug Services of the MOH of the Republic of Liberia, and a representative of USAID/Liberia (see Annex 1) met for four days to review, discuss, and finalize the draft Act to establish a Medicines Regulatory Authority. It will be called the Liberian Medicines and Health Products Regulatory Authority (LMHRA), and hereafter will be referred to as the Authority.

2. The finalized draft Act includes the following main elements:
   - The Act establishes a new Authority as an autonomous agency, responsible for regulating medicines, health products, and cosmetics.
   - The Authority will be governed by a Board of Directors, Director General, and Managing Team.
   - The Act details the functions of the Authority as a whole, as well as the duties of the Board of Directors and the Director General respectively.
   - The Act states that the new Authority shall observe Good Regulatory Practices, including transparency and accountability.

3. The full version of the agreed text is attached in Annex 2.
4. Discussion

- The DQI team strongly recommended to the LMRC that the Board of Directors play an advisory role, rather than a managerial role. However, the LMRC insisted on a governing board and pointed out that this was fully in line with current practices in the country. In this context and in response, the DQI team ensured that relevant clauses were included in the draft stating that the Director General is responsible for the day-to-day management of the Authority, as well for approving the marketing authorizations and licenses.

- Another major point of discussion was the role or authority of the MOH, and by the same token, the link between the Authority and the MOH. In the current version of the draft Act, the role of the MOH is limited to recommending the Director General and Members of the Board of Directors for appointment by the President of Liberia. The MOH is also represented on the Board by the MOH Chief Pharmacist. It remains to be seen whether the Minister of Health will agree and sign off on the Act as it is.

The LMRC strongly preferred that the Authority be fully independent of the MOH. It cannot be said with certainty at this point whether this is a positive or negative result. On one hand, the Authority is part of the health system and, thus, there is ground for arguing that the links between the MOH and the Authority should be stronger than currently provided for in the draft Act. On the other hand, and depending on the political context, it may indeed be preferable that the Authority has full independence in its registration of medicines and licensing of premises. Furthermore, the draft Act only regulates part of what ultimately constitutes a national pharmaceutical policy and it can be expected that the MOH will keep full authority of such policy areas as drug financing and rational use.

- It was impossible to finalize the section of the Act dealing with (i) violations and the corresponding civil and criminal penalties, and (ii) the right of appeal, due to the fact that the Liberian penal code currently does not contain the necessary provisions.

5. Recommendations to the LMRC

- The DQI team received assurances from the LMRC that the attached draft Act would be submitted as is to the Minister of Health and then to the Legislature. The DQI team hopes and strongly recommends that the current version will indeed be submitted for vote without significant modifications.

- The DQI team also recommended, and the LMRC agreed, that the LMRC members should immediately focus on gathering support among the members of the Legislature to ensure smooth passage of the draft Act into law.

- The DQI team recommended that the LMRC also immediately start drafting regulations dealing with violations and penalties related to this Act.
III. USAID and MOH Debriefing

1. On February 6 the DQI team debriefed Dr. Kassahun Belay, Dr. Filiberto Hernandez, and Mr. Kaa Williams at the USAID/Liberia Mission on the results of the trip. The presentation led to a brief discussion of the next steps as well as the need to find additional funding to permit continuation of the DQI support activities. The DQI team committed to preparing a concrete proposal and justification for the USAID Mission to form the basis for an appropriate funding allocation in FY09.

2. The DQI team also debriefed the Ministry of Health, in particular Mrs. Jessie Duncan and her staff, on the accomplishments. The MOH representatives expressed their satisfaction with the results and thanked the USAID Mission for providing technical support. The Chief Pharmacist of the MOH, Rev. Tijli Tyee, who was also present at the debriefing and had been part of the workshop, went as far as stating that “he was in love with what was accomplished this week.” The MOH representatives said they would read the draft Act carefully and provide feedback.

IV. Next Steps

- Pending available funding, DQI will assist the Authority in completing all the necessary legislation to implement the subject Act.

- Pending available funding, DQI will support the Ministry of Health and the National Malaria Control Program in the establishment of an operational National Quality Control Laboratory (NQCL).

- DQI will prepare a proposal and justification of the abovementioned two items by April 30, 2009.

- DQI will prepare a master plan for the development of the NQCL, which will represent the last deliverable under the DQI FY09 work plan.

- DQI will provide reference standards for the NDS Lab and will help the lab carry out basic tests using Minilabs®. DQI staff will remotely monitor the progress made by NDS analysts.
**ANNEX 1**

**LIST OF PARTICIPANTS**

**USP DQI WORKSHOP TO REVIEW AND FINALIZE THE DRUG LEGISLATION OF LMHRA (FEB. 3-4-5, 2009)**

<table>
<thead>
<tr>
<th>NAME</th>
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<tbody>
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<td>Registrar, Pharmacy Board</td>
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<td>PBL, Jr. Legal Practitioner</td>
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<td>TOLBERT G. NYENSWAH</td>
<td>NMCP / MOHSW</td>
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<td>JOSEPH N.B. JIMMY</td>
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<td>LMRC</td>
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<td>J. NATHANIEL B. WOART</td>
<td>Pharmacy Board</td>
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<td>JULIUS JANAFO</td>
<td>NMCP / MOHSW</td>
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The Liberia Medicines and Health Products Regulatory Authority (LMHRA) Proposed Act to the National Legislature

PREAMBLE

WHEREAS it is recognized that health care plays a significant role in securing proper life and productivity of the people as well as economic development of the country and it is recognized that medicines and health products play a vital role in the health care of humans as well as animals

WHEREAS it is found necessary to ensure the quality, safety, and efficacy of medicines and health products used in the Republic of Liberia;

WHEREAS it is incumbent upon the Government of the Republic of Liberia to promulgate laws to ensure good quality, safe and efficacious medicines and health products for the enhancement of quality health services in the country;

WHEREAS, to achieve these ends, it is found necessary to establish an effective Medicines and Health Products Regulatory Authority;

THEREFORE, in keeping with the Constitution of the Republic of Liberia, it is hereby proclaimed:

PART ONE

General Provisions

I. Title

This Act shall be cited as the “Liberia Medicines and Health Products Regulatory Authority Act” No______________.

II. Purpose of the Act

1. To ensure that, in the national medicine supply system, safe, effective, and good quality medicines reach the Liberian public
2. To protect the Liberian public from the harmful effects of counterfeit and substandard medicines and health products

3. To ensure fair trade practices in medicines and health products

4. To fight illegal trade in medicines including counterfeit and adulterated medicines and health products

III. Definitions

In this Act, unless or otherwise provided as per context:

1. “Medicine” means any substance or mixture of substances used in
   a. the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in man or animal.
   b. restoring, correcting, or beneficial modification of organic or mental functions in man or animal

   This shall include traditional medicines, narcotic drug and psychotropic substances, blood and blood products, vaccines, sera, radiopharmaceuticals, but not health products.

2. “Narcotic Drug” means any substance subject to control according to the Single Narcotic Drugs Conventions, 1961, adopted by the United Nations and ratified by the Republic of Liberia. This shall also include any substance categorized by the Authority as a narcotic drug.

3. “Psychotropic Substance” means any substance subject to control according to the Conventions on Psychotropic Substances, 1971, adopted by the United Nations and ratified by the Republic of Liberia. This shall also include any substance categorized by the Authority as a psychotropic substance.

4. “Cosmetic” means any preparation intended to be applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance without affecting the body’s structure or functions.

5. “Health Product” includes:
   a. “Medical Device” means any instrument that may be used for diagnosis, treatment or mitigation of a disease in man or animal.
   b. “Medical Supply” means any article that may be used on the inner or outer part of the body for diagnosis or treatment of a disease in man or animal. This includes: suturing materials, syringes, needles, bandages, gauze, cotton, artificial teeth, chemicals, and X-Ray film and other similar articles.

7. "Packaging Material" means any article that may be used for filling, inserting, wrapping, or packing medicines and health products. The primary package is the container directly in contact with the product, and the secondary package is whatever covers the primary package. This includes packaging of excipients and active pharmaceutical ingredients.

8. "Label" means any material that is printed or affixed to a packaging material and that provides the necessary information about a medicine and this includes a leaflet.

9. "Counterfeit Medicine" is one that is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeit can apply to branded or generic medicines; counterfeit products may include products with correct ingredients, with the wrong ingredients, without ingredients, with insufficient active ingredients, or with fake package.

10. “Substandard Medicine” is one that does not comply with the quality standards adopted by the LMHRA.

11. “Adulteration” is tampering in such a way as to affect the authenticity of the original product.

PART TWO

Administrative and Organizational Provisions

I. Establishment

1. The Liberia Medicines and Health Products Regulatory Authority, hereinafter referred to as "the Authority", is hereby established by this Act.

2. The Authority shall be autonomous and accountable to the President of the Republic of Liberia through the Minister of Health and Social Welfare.

3. The head office of the Authority shall be in Monrovia and it may have county offices.
II. Functions and Duties of the Authority

1. The Authority shall have the functions and duties to:
   a. Conduct registration of medicines and health products regulated by this Act
   b. Issue licenses or permits for premises and personnel to engage in the manufacture, import, export, transit, supply, storage, distribution and sale of products regulated under this Act
   c. Suspend, cancel, and revoke such licenses or permits as deemed necessary
   d. Establish inspectorate and conduct inspection of premises where medicines and health products are manufactured, stored, distributed, supplied and sold
   e. Establish and operate a quality control laboratory
   f. Conduct post-marketing surveillance of medicines and health products regulated by this Act
   g. Conduct pharmacovigilance of medicines and health products regulated under this Act
   h. Issue warnings and conduct recalls of products
   i. Regulate the conduct of clinical studies
   j. Prepare, keep, and update registry for medicines and health products approved for marketing in the Republic of Liberia
   k. Keep registry of licensed premises and persons
   l. Set standards of quality, safety, and efficacy of medicines and health products regulated by this Act
   m. Prepare draft regulations and present same for promulgation
   n. Develop, print and disseminate guidelines, procedures, guidance and other materials necessary for effective implementation of the functions of the Authority
   o. Provide current and truthful information on medicines and health products to professionals and to the general public
   p. Regulate advertising and promotion of medicines and health products
   q. Be responsible for its human resources development
   r. Promote, monitor and evaluate the implementation of this Act
   s. Receive and investigate complaints of violations in contravention of the Act and its regulations, and impose appropriate sanctions as prescribed in the regulations
   t. Carry out other functions as deemed necessary for the implementation of this Act

2. In performing its functions, the Authority shall apply principles of Good Regulatory Practices by:
   a. Ensuring transparency and accountability
   b. Promoting stakeholders participation and building consensus
   c. Observing a code of conduct and managing any possible conflict of interest
III. Organization of the Authority

The Authority shall have:
   a. A Board of Directors
   b. A Director-General responsible for running the Authority
   c. Managers heading different units of the Authority
   d. A Managing Committee composed of the Director-General and the Managers

IV. Board of Directors

1. The Board of Directors shall have nine members to be appointed by the President of the Republic of Liberia through the Minister of Health and Social Welfare

2. The Board of Directors shall serve for a period of three years

3. The Board of Directors shall consist of the following members, at least three of which shall be women:
   a. A pharmacist who shall be appointed by the President of the Republic of Liberia to chair the Board of Directors
   b. The Chief Pharmacist representing the Minister of Health and Social Welfare
   c. A representative of the Pharmaceutical Association of Liberia
   d. A representative of the School of Pharmacy of the University of Liberia
   e. A representative of the Liberia Medical and Dental Association
   f. A representative of the Ministry of Finance
   g. A legal person representing the Ministry of Justice
   h. A veterinarian
   i. A representative of the consumer interest group/association

The Director General of the Authority shall be a non-voting member of the Board of Directors and shall serve as Secretary to the Board of Directors.

4. The Board of Directors shall have the powers and duties to:
   a. Approve regulations for implementation of this Act
   b. Approve the strategic plan of LMHRA
   c. Approve the annual work plan and budget of the Authority
   d. Review the quarterly reports presented by the Director General
   e. Monitor and evaluate the implementation of this Act
   f. Approve the Managers recommended by the Director General
   g. Establish committees whenever deemed necessary
5. **Meetings of the Board**

Without prejudice to the provisions of this Act, the Board of Directors may issue its own rules of procedures.

**V. The Director General of the Authority**

1. The Director General of the Authority shall be appointed by the President through the Minister of Health and Social Welfare

2. The Director General shall recommend the Managers to be appointed by the Board of Directors

3. The Director General shall be the administrative and technical head of the Authority and shall direct and administer the day to day activities of the Authority.

4. The Director General shall, in consultation with his Managers, exercise the following duties:
   a. Exercise the functions and duties of the Authority specified under Article … of this Act
   b. Administer personnel of the Authority following the basic principles of the Liberia Labor Law No……
   c. Prepare and summit to the Board of Directors the annual plan and budget of the Authority and implement same upon approval;
   d. Effect payments in accordance with the approved budget in line with the approved plan of action (POA) of the Authority;
   e. Submit quarterly reports to the Board of Directors.
   f. Establish technical committees with the approval of the Board of the Directors.
   g. Approve registrations for medicines and health products upon recommendation from the medicines evaluation committee.
   h. Approve licenses for premises.

5. The Director General may delegate part of his functions to other employees of the Authority to the extent necessary for the efficient performance of its activities.
VI. Funding

1. The funds of the Authority shall be drawn from the following sources:
   a. Budget allocated by the government,
   b. Fees collected for services provided
   c. Any other authorized sources devoid of conflict of interest

2. The Authority shall open and maintain bank accounts in the name of the Authority.

VII. Books of Accounts

1. The Authority shall keep complete and accurate books of accounts.

2. The books of accounts and other financial documents of the Authority shall be audited annually by the Auditor General of the Republic of Liberia.

3. The Board of Directors may also choose to engage the services of an external auditor.

VIII. Delegation of Powers and Duties

The Authority may delegate part of its powers and duties to other government agencies to the extent and whenever it is deemed necessary for the efficient performances of its activities.

PART THREE

Specific Provisions

I. Registration of Medicines and Health Products

1. No medicines and health products, whether produced locally or imported, shall be put into use in the Republic of Liberia unless it is duly registered by the Authority.

2. Medicines registration licenses shall be granted by the Authority only upon recommendation made by the medicines evaluation committee.

3. The registration shall be done in accordance with the regulations to be issued for the implementation of this Act.
II. Control of Import, Export, and Transit of Medicines and Health Products

1. No person/organization shall import, export, or transit into or out of the Republic of Liberia medicines and health products regulated by this Act unless the person/organization has been issued a license or permit by the Authority.
2. Conditions for issuance of license or permit shall be stipulated in regulations promulgated by the Authority.

III. Supply, Storage, Distribution and Sale of Medicines and Health Products

1. No person/organization shall supply, store, distribute and sell medicines and health products regulated by this Act unless the person/organization has been issued a license or permit from the Authority.
2. Conditions for issuance of license or permit shall be stipulated in regulations promulgated by the Authority.

IV. Manufacture of Medicines and Health Products

1. No person/organization shall manufacture medicines and health products regulated by this Act unless the person/organization has been issued a license or permit from the Authority.
2. Conditions for issuance of license and permit shall be stipulated in regulations promulgated by the Authority.

V. Clinical Studies

1. No person/organization shall conduct therapeutic and non-therapeutic clinical studies without the authorization of the Authority.
2. Conditions for authorization of therapeutic and non-therapeutic clinical studies shall be stipulated in regulations.

VI. Advertising and Promotion of Promotion and Health Products

1. No person shall advertise or promote medicines and health products regulated by this Act without the Authority.
2. Conditions for issuance of license and permit shall be stipulated in regulations promulgated by the Authority.
VII. Donations of Medicines and Health Products

1. Donated medicines and health products must respond to national needs.

2. To the extent possible, donated medicines and health products must be registered by the Authority.

3. In case of emergency and disasters, the Authority must expedite or waive the registration of donated medicines.

PART FOUR

Narcotic Drugs and Psychotropic Substances

1. A special license issued by the Authority shall be required to import, export, manufacture or distribute narcotic substances.

2. No person or organization shall import, export, manufacture, store or distribute narcotic and psychotropic substances, unless said person or organization has been issued a special license by the Authority.

3. The management and standard for prescription shall be set forth in the regulation pursuant to this Act.

PART FIVE

Radiopharmaceuticals

1. The Authority shall issue regulations and directives regarding the storage, distribution, use and disposal of radiopharmaceuticals in accordance with the recommendations that it may receive from the International Atomic Energy Agency (IAEA).

2. No person/organization shall manufacture, import, distribute or sell radiopharmaceuticals unless the said person/organization has obtained a special permit from the Authority.
3. The regulations and standards for the management of radiopharmaceuticals shall be set forth pursuant to this Act.

PART SIX

Offenses and Right of Appeal

1. Any person/organization who contravenes any section of this Act or any regulations issued under this Act commits a punishable offense and shall be prosecuted.

2. Any person/organization not satisfied by a decision of the Authority has the right to appeal. The appeal system shall include an independent administrative system as well as Court of Law.

PART SEVEN

Miscellaneous

1. Repeal

The passage of this Act into law will repeal any provision of the Public Health Law, July 1976, running contrary to the present Act and the regulations thereof.

2. Transitory Provision

Licenses issued prior to the coming into force of this law shall be deemed to have been issued under this Act and be subject to the provisions of this law and regulations and directives issued pursuant to this law.