

Medicines & Health Products Regulatory Authority (LMHRA) Act

AN ACT TO ESTABLISH THE LIBERIA MEDICINES AND HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA) OF 2010

PREAMBLE

WHEREAS, it is recognized that health care plays a significant role in securing well-being 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

REALIZING the necessity to ensure the quality, safety and efficacy of medicines and health products used in the Republic of Liberia;

NOTING THAT, 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; and

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

NOW THEREFORE, It is enacted by the Senate and House of Representatives of the Republic of Liberia In Legislature assembled:

PART I ESTABLISHMENT OF THE AUTHORITY

Section 1

That from and immediately upon the passage of this Act there is hereby established the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010.

Section 2: Short Title

This Act shall be cited also as Liberia Medicines and Health Products Regulatory Authority (LMHRA).

PART II GENERAL PROVISIONS

Section 1: Definitions

In this Act unless the context otherwise requires, the following words and phrases shall have the meanings as ascribed to them in this section.

1. "**Medicine**" means any substance or mixture of substances intended for use in:

- a. the diagnosis, treatment, mitigation, or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof in man or animal, or
- b. restoring, correcting, or beneficial modification of organic or mental functions in man or animal.
- c. Medicine shall include traditional medicines, narcotic drugs, psychotropic substances, blood and blood products, vaccines, sera, and radiopharmaceuticals, but not health products as defined herein.

2. "**Narcotic Drug**" means any substance subject to control according to the Single Narcotic Drugs Conventions, 1962, 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**," which means any instrument that is not a medicine, as defined herein, that is intended for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or symptoms thereof, in human or animal, or restoring correcting, or beneficial modification of organic or mental functions in human or animal; and

b. "**Medical Supply**," which means any article that is intended for diagnosis, treatment, mitigation or prevention of a disease disorder, abnormal physical or mental state, or symptoms thereof, in human or animal, or restoring, correcting, or beneficial modification of organic or mental functions in human or animal. This includes suturing materials, syringes, needles, bandages, gauze, cotton, artificial teeth, chemicals, and X-Ray film and other similar articles.

6. "**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.

7. "**Label**" means any material that is printed or affixed to packaging material, including a leaflet, which provides the necessary information about a medicine.

8. "**Counterfeit Medicine**" means a medicine that is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeit products may be branded or generic medicines, and may include products with the correct ingredients, with the wrong ingredients, without ingredients, with insufficient active ingredients, or with fake packaging materials.

9. "**Substandard Medicine**" means a medicine that does not comply with the applicable quality standards adopted by the Authority.

10. "**Adulteration**" means the causing or doing any act that affects the purity, potency, strength or content of a product, so that it is not of good quality, safe and effective, or not what it purports to be.

11. "**Authority**" herein means the Liberia Medicines and Health Products Regulatory Authority established under Part I, Section 1 of this Act.

12. "**Radiopharmaceutical**" means an article intended for diagnostic or therapeutic use that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear radiation.

13. "**Pharmacovigilance**" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problem.

PART III 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 substandard and counterfeit medicines and health products.

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

4. To promulgate regulations to fight illegal trade in medicines, including counterfeit and adulterated medicines and health products.

5. To conduct or facilitate necessary research and development, promote Pharmacovigilance, and disseminate timely drug information.

PART IV ADMINISTRATIVE AND ORGANIZATIONAL PROVISIONS

Section 1. Accountability and Offices

(1) The Authority shall be autonomous and accountable, to the President of the Republic of Liberia and shall submit an annual report of its activities to the Legislature.

(2) The Authority shall have its Head Office in the capital, Monrovia and may establish county offices, contingent on its necessities and requirements.

Section 2. Functions and Duties of the Authority.

(1) The functions and duties of the Authority shall include:

- a. Conduct registration of medicines and health products;
- b. Issue licenses or permits for premises and personnel to engage in the manufacture; import, export, transit in or out of the Republic of Liberia, supply, storage, distribution, or sale of medicines and health products, excluding retail pharmaceutical outlets;
- c. As and when deemed necessary by the Authority suspend, cancel, or revoke such license or permits referred to in Part II, Section 2.1(b) in accordance with regulations promulgated by the Authority under this Act and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law;
- d. Establish an inspectorate and conduct inspections of premises where medicines or health products are manufactured, stored, distributed, supplied and sold;
- e. Confiscate expired, substandard, counterfeit, or unregistered medicines in accordance with regulations promulgated by the Authority under this Act, and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law;
- f. Establish and operate quality control laboratories to ensure safe, effective, and good quality medicines and health products for domestic and foreign markets;
- g. Conduct post-marketing surveillance of medicines and health products;
- h. Conduct Pharmacovigilance of medicines and health products;,
- i. Issue warnings and conduct recalls of products in accordance with regulations promulgated by the Authority under this Act, and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law;
- j. Regulate the conduct of clinical studies of medicines and health products;
- k. Prepare, keep, and update a registry of medicines and health products registered and approved for marketing in the Republic of Liberia
- l. Set standards of quality, safety, and efficacy of medicines and health products;

- m. Promulgate regulations as necessary to meet its responsibilities under this Act, including regulations providing for administrative hearings necessary for effective enforcement of this Act;
 - n. Develop and disseminate guidelines, procedures, guidance and other materials necessary for effective implementation of the functions of the Authority;
 - o. Provide current and unbiased information on medicines and health products to health care professionals and 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 regarding alleged violations of the Act or any regulations promulgated by the Authority, and impose appropriate sanctions in accordance with regulations promulgated by the Authority under this Act, and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law;
 - t. Establish and collect charges or fees for services rendered by the Authority; and
 - u. Carry out other functions as deemed necessary by the Authority for the effective and fair implementation of this Act.
1. In performing its functions, the Authority shall apply principles of Good Regulatory Practices, which include but not limited to:
- a. Ensuring transparency and accountability;
 - b. Promoting stakeholders' participation and building consensus; and
 - c. Observing a code of conduct and managing any potential conflict of interests.

Section 3. Organization of the Authority

The Authority shall have:

- 1) A Board of Directors
- 2) A Managing Director, who shall be responsible for running the Authority;
- 3) Managers heading different units of the Authority; and

4) A Managing Committee composed of the Managers, with the Managing Director as its head.

Section 4. Board of Directors

1) The Board of Directors shall have eleven (11) voting members, to be appointed by the President of the Republic of Liberia.

2) The Board of Directors shall consist of the following members, at least three (3) of whom shall be women:

a. A qualified Liberian 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 Ministry of Health and Social Welfare;

c. The head of the Pharmacy Board;

d. A lawyer representing the Ministry of Justice;

e. The head of Customs, representing the Ministry of Finance;

f. The head of the National Bureau of Standards, representing the Ministry of Commerce;

g. A representative of the School of Pharmacy of the University of Liberia:

h. A representative of the Liberia Medical and Dental Council;

a. A representative of the Pharmaceutical Association of Liberia

b. A veterinarian;

c. A representative of an appropriate consumer interest group or association; and

d. The Managing Director of the Authority, who shall serve as secretary to the Board of Directors, and who shall be a non-voting member.

2. 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 the Authority;

c. Approve the annual work plan and budget of the Authority;

d. Review the quarterly reports presented by the Managing Director;

- e. Monitor and evaluate implementation of this Act;
 - f. Approve the individuals recommended to be Managers by the Managing Director;
 - g. Establish committees whenever it deems necessary; and
 - h. By a two-thirds (2/3) majority vote of the full membership of the Board of Directors, remove Managers or recommend to the President for removal of any member of the Board of Directors, in either case only for acts incompatible with the Authority's or Board's rules or regulations.
3. Without prejudice to the provisions of this Act, the Board of Directors shall issue its own rules of procedure for the conduct of meetings, and establish a code of conduct governing the activities of the Board and members of the Board. The tenure of each Board shall be two (2) years.

Section 5. The Managing Director of the Authority

- 1) The Managing Director, a qualified Liberian Pharmacist, shall be the administrative and technical head of the Authority, and shall direct and administer the day-to-day activities of the Authority.
- 2) The Managing Director shall recommend the Managers to be appointed by the Board of Directors.
- 3) The Managing Director shall in consultation with his Managers exercise the following duties:
 - a. Exercise the functions and duties of the Authority specified under Part IV, Section 2.1 of this Act;
 - b. Administer personnel of the Authority consistent with the basic principles of the Liberian Labor Law;
 - c. Prepare and submit to the Board of Directors the annual plan and budget of the Authority and implement upon approval;
 - d. Effect payments in accordance with approved budget in line with the approved annual plan of the Authority;
 - e. Submit quarterly reports to the Board of Directors;
 - f. Establish technical committees, including a medicines evaluation committee, with the approval of the Board of Directors;
 - g. Approve registration of medicines and health products upon recommendation of the

medicines evaluation committee;

h. Approve licenses for pharmaceutical premises as referred to in Part IV, Section 2.1(b).

4. The Managing Director may delegate part of his functions to other employees of the Authority to the extent necessary for the efficient performance of its activities.

5. In the event of the occurrence of a vacancy emanating from the death, resignation, retirement or dismissal of the Managing Director, the President of Liberia shall designate one of the other Managers as Acting Managing Director, pending the appointment of the Managing Director proper.

Section 6. Administration of the Authority and Delegation of Powers and Duties

1) The Authority shall have the power to determine the level of officers and employees deemed required, and to establish the positions thereof to optimize the performance of the Authority's functions.

2) By general or special order in writing, the Authority may temporarily delegate any part of its powers and duties to other government agencies, to the extent the Board of Directors deems it necessary for the efficient performance of the Authority's functions. Such delegation shall be limited to a specific time period, and restricted to those functions specifically identified in the written order of delegation.

Section 7. Funding

The funds of the Authority shall be drawn from the following sources:

i. Budget allocated by the government;

ii. Fees collected for services provided; and

iii. Any other authorized sources that are devoid of any conflict of interest.

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

Section 8. Books of Accounts

1) The Authority shall ensure that its Financial Department keeps complete and accurate books of accounts in accordance with any applicable financial laws of Liberia, whether currently in existence or enacted in the future, and Generally Accepted Accounting Principles (where applicable). The Authority shall also ensure that its Internal Audit Unit conducts regular audits to guide compliance with such financial laws and accounting principles.

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.

PART V SPECIFIC PROVISIONS

Section 1. Registration of Medicines and Health Products

1) No medicine or health product, whether manufactured 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. The registration shall be done in accordance with regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such licenses.

Section 2. 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 any medicine or health product, unless the product is duly registered by the Authority and the person/organization has been issued a license or permit by the Authority for the same.

2) The conditions of issuance of a license or permit for the import, export, or transit of medicines or health products shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such licenses or permits.

Section 3. Supply, Storage, Distribution, and Sale of Medicines and Health Products

1) No person/organization shall supply, store, distribute or sell any medicine or health product unless the product is duly registered by the Authority, and the person/organization has been issued a license or permit by the Authority for the same.

2) The conditions of issuance of a license or permit for the supplying, storage, distribution, or sale of medicines or health products shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance renewal, suspension, cancellation and revocation of such licenses or permits.

Section 4. Manufacture of Medicines and Health Products

1) No person/organization shall manufacture any medicine or health product, unless the person organization has been issued a license or permit by the Authority.

2) The conditions of issuance of a license or permit for the manufacture of medicines or health products shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such licenses or permits.

Section 5. Clinical Studies

- 1) No person/organization shall conduct clinical studies in humans or animals of medicines or health products without the authorization of the Authority.
- 2) The conditions for authorization of such clinical studies shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such authorizations.

Section 6. Advertising and Promotion of Medicines and Health Products

- 1) No person/organization shall advertise or promote any medicine or health product in a way that is false or misleading.
- 2) The Authority shall promulgate regulations that: (i) establish standards for determining when any advertising or promotional activity is false or misleading, (ii) provide for review of advertising and promotional activities or materials, and (iii) provide for enforcement of the prohibition of false or misleading activities or materials.

Section 7. Donations of Medicines and Health Products

- 1) Donated medicines and health products must respond to national needs identified or established by the Ministry of Health and Social Welfare.
- 2) Donated Medicines and health products are subject to the provisions of Part V, as applicable.
- 3) In the case of emergency or disaster, the Authority may expedite or, as necessary, waive the registration of donated medicines or health products.

PART VI NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

- 1) No person/organization shall import, export, transit into or out of the Republic of Liberia, manufacture, store, distribute sell, prescribe, dispense or administer any narcotic drug or psychotropic substance, unless the person/organization has been issued a special license for such purpose by the Authority. This special license shall be in addition to any license, permit or other requirement or restriction of Part V.
- 2) No person/organization shall dispense or administer any narcotic drug or psychotropic substance except in accordance with a valid prescription from a licensed health care practitioner authorized to prescribe such products.
- 3) The conditions for issuance of a special license for the import, export, transit manufacture, storage, distribution, sale of narcotic drugs or psychotropic substances shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such special licenses.

4) The conditions for the prescribing, dispensing, or administration of narcotic drugs or psychotropic substances shall be stipulated in regulations promulgated by the Authority.

PART VII RADIOPHARMACEUTICALS

1) No person/organization shall import, export, transit into or out of the Republic of Liberia, manufacture, store, distribute, sell or dispose of any radiopharmaceutical unless the person/organization has been issued a special permit for such by the Authority. This special permit shall be in addition to any license, permit or other requirement or restriction of Part V.

2) The conditions for issuance of a special permit for the import, export, transit, manufacture, storage, distribution, sale or disposal of radiopharmaceuticals shall be stipulated in regulations promulgated by the Authority that shall be in accordance with any recommendations received from the International Atomic Energy Agency, and shall provide for the issuance, renewal, suspension, cancellation and revocation of such special permits.

PART VIII VIOLATIONS AND ENFORCEMENT

Section 1. Administrative Sanctions

Any person/organization who cause or takes any action, or any failure to act that violates any provision of this Act or any regulation promulgated under this Act may be subject to enforcement action in accordance with the provisions of this Part VIII, Section 1. The civil administrative penalties provided for herein are in addition to any applicable criminal penalties.

1) Confiscation

Any medicine or health product that has been put into use, imported, exported, transited into or out of the Republic of Liberia, supplied, stored, distributed, sold, offered for sale, manufactured, used in a clinical study in humans, advertised or promoted, or donated in violation of the Act or any regulation promulgated under this Act may be confiscated by the Authority and destroyed or otherwise disposed of or used as the Authority deems appropriate and is consistent with this Act.

2) License or Permit Revocation

Any person/organization who causes or takes any action, or any failure to act, that violates this Act or any regulation promulgated under this Act may have its license, permit or special permit suspended, revoked or withdrawn.

3) Administrative Penalties

Any person/organization who causes or takes any action or any failure to act, that violates this Act or any regulation promulgated under this Act may be subject to administrative penalties, as follows:

- i. A penalty of not more than \$1,500 United States dollars may be imposed for impeding any inspection or investigation carried out under the Act.
- ii. A penalty of not more than \$500 United States dollars may be imposed for any action or failure to act involving an unregistered drug in violation of Part V.
- iii. A penalty of not more than \$500 United States dollars may be imposed for any importation, exportation or transit into or out of the Republic of Liberia in violation of Part V, Section 2.
- iv. A penalty of not more than \$500 United States dollars may be imposed for any supply, storage, distribution, sale or offer to sell in violation of Part V Section 3.
- v. A penalty of not more than \$500 United States dollars may be imposed for any manufacturing in violation of Part V, Section 4.
- vi. A penalty of not more than \$500 United States dollars may be imposed for any clinical study in humans in violation of Part V, Section 5.
- vii. A penalty of not more than \$500 United States dollars may be imposed for any advertising or promotion in violation of Part V, Section 6.
- viii. A penalty of not more than \$500 United States dollars may be imposed for any donation of medicines or health products in violation of Part V, Section 7.
- ix. A penalty of not more than \$500 United States dollars may be imposed for any importation, exportation, transit into or out of the Republic of Liberia manufacturing, storage, distribution, sale, offer to sell, dispensing or administering of, or issuance of a prescription for, any narcotic drug or psychotropic substance in violation of Part VI.
- x. A penalty of not more than \$500 United States dollars may be imposed for any importation, exportation, transit into or out of the Republic of Liberia, manufacturing, storage, distribution, sale, offer to sell, or disposal of any radiopharmaceutical in violation of Part VII.
- xi. As deemed necessary, but no more frequently than once every two years, the Authority may adjust the maximum penalties identified herein.

b. Regulations

- i. The Authority shall promulgate regulations to establish the process, procedures, and standards by which any of the penalties of this Part VIII, Section 1 may be imposed. Such process shall include notice to the person/organization, a right to an administrative hearing, appeal within the Authority, and judicial review.

ii. The Authority shall promulgate regulations to establish the process, procedures and standards by which any adjustment in the civil penalties provided for in Part VIII, Section 1.3 shall be made.

iii. Any regulation promulgated by the Authority under this Part VI shall be consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of the law.

Section 2. Civil Liability

Any person/organization that causes or takes any action, or any failure to act, enumerated in Part VIII, Section 1, will be liable in tort for any and all damages caused by such action or failure to act.

Section 3. Criminal Penalties

Any person/organization who causes or takes any action, or any failure to act, enumerated in Part VIII, Section 1 may be subject to criminal prosecution in accordance with the provisions of this Part VIII, Section 2 or the Penal Code of the Republic of Liberia, whichever act provides a greater length of imprisonment or higher fine. The criminal penalties provided for herein are in addition to any applicable civil administrative penalties.

1) Initial Violation

Any person/organization who causes or takes any action, or any failure to act enumerated in Part VIII Section 1 shall be guilty of a first degree misdemeanor.

2) Second and Further Violations; Violation with Intent to Defraud or Mislead
Notwithstanding the provisions of Part VIII, Section 3.1, any person/organization who commits any such violation after a conviction under this section has become final, or commits such a violation with the intent to defraud or mislead, shall be guilty of a third degree felony.

PART IX MISCELLANEOUS

Section 1. Miscellaneous

1. 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. With the enactment of this Act, all drug control matters as promulgated in the DEA Act shall be restricted to only illicit drugs as recognized by the United Nations conventions of 1961, 1971, and 1988.

3. With the enactment of this Act, all regulatory functions of the Pharmacy Board of Liberia shall be surrendered to the Authority, except for the following functions which shall remain the responsibility of the Pharmacy Board of Liberia, notwithstanding any provisions of this Act or any regulations promulgated under this Act:

a. Administer examinations for the qualification of graduate pharmacists and dispensers who have completed the requirements for licensure.

b. Register and maintain the register of all pharmacists and dispensers practicing in Liberia.

c. Supervise and control the ethical behavior of practicing pharmacists and dispensers in Liberia.

Ensure the continuing professional development of pharmacists and dispensers.

d. Inspect retail pharmaceutical outlets for annual registration documents, conditions of premises, and qualifications of dispensers in stores.

e. Issue permits to retailers annually.

f. Evaluate curricula and issue annual permits to pharmaceutical training institutions.

g. Set standards and define requirements for establishing and operating retail pharmaceutical outlets.

4. Licenses issued prior to the coming into force of this Act shall be deemed to have been issued under, and subject to the provisions of this Act and any regulations promulgated under this Act.

Section2. Effective Date

This Act shall take effect immediately upon the publication into handbills.

ANY LAW TO THE CONTRARY NOTWITHSTANDING

Approved: September 29th, 2010

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