# **REPUBLIC OF LIBERIA**



# MINISTRY OF HEALTH AND SOCIAL WELFARE

# NATIONAL DRUG POLICY (2001)

Note: This document was recently scanned (July 21, 2010) from a hard copy of the 2001 National Drug Policy and may contain some typographical errors.

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#### FOREWARD

Making of a national drug policy for Liberia at this moment is timely, because it is done at the time when Liberia is affected by a multitude of problems related to the management and use of drugs as well as dwindling donor support for drug supplies.

While drugs are needed for disease treatment and, when used properly, for the alleviation of suffering, it is realized that the availability, proper management, and particularly the rational use of drugs are imperative. This policy document is intended to address the problems of the availability and management, including the rational use of drugs.

Cardinal to a national drug policy is the concept of essential drugs, the application of which the Government of Liberia has already developed a national essential drugs list (NEDL).

It is hoped that the National Drug Policy of Liberia, together with its other complementary documents such as the National Standard Treatment Guidelines and National Drug Formulary, will coordinate all of the activities and guide all actors in the Pharmaceutical Sector, including complementary medical practice.

I take pleasure to note that the document takes into account, inter alia, the vision of the present government - Vision AD 2024, and particularly, the need to provide quality health care for the citizens and residents of Liberia.

Also, I wholeheartedly endorse the idea that the document includes the traditional components of a holistic national drug policy, which range from legislative and regulatory framework to technical cooperation among countries. These provisions include drug quality assurance; drug product registration; regulation of prescription and dispensing practices; implementation of global initiatives such as the WHO Certification Scheme; International Property Rights; control of abuse, illicit production and trafficking of drugs, etc.

On behalf of the Government of Liberia and the Ministry of Health and Social Welfare, special and sincere thanks are extended to the WHO for both financial support and technical assistance throughout the stages of developing of this document. Likewise, I acknowledge the input of other partners within and outside the GOL Sector.

Making a policy is different from implementing its provisions. I am confident that Government will strive to ensure full implementation of the provisions of this document, and periodically revise it to suit current health realities regarding drugs.

Peter S. Coleman, MD., MS., FWACS Honorable Minister Ministry of Health & Social Welfare, R.L.

June 2001

#### ACKNOWLEDGMENTS

The process of making the Liberia National Drug Policy, the first of its kind, was supported by a broad spectrum of contributors who represented several GOL agencies, parastatals, UN agencies, especially, the World Health Organization which provided consultants and funds for the development of the National Drug Policy. Our profound gratitude goes to other international and national agencies, and interest groups for their assistance.

Owing to the limited space, we are constrained to mention only those agencies that took part in the workshop for review and consensus- building on the draft of the policy.

The participants included, GOL agencies like the Ministry of Finance (Customs and Excise Division), Ministry of Justice (Police Force); the National Port Authority, the John F. Kennedy Memorial Medical Center; and the National Drug Service. Others were the School of Pharmacy and the A.M.Dogliotti College of Medicine (University of Liberia), the Christian Health Association of Liberia, the Liberia Pharmaceutical Business Community, the Consortium of international NGOS, the European Union, the Pharmacy Board and the Pharmaceutical Association of Liberia, and the Liberia Bar Association (represented by its Vice President Clir. Marcus R. Jones, its vice president).

Participation of the departments and their other divisions and programs in the Ministry of Health and Social Welfare will never be forgotten. These included the Division of Nursing; the Division of Occupational and Environmental Health, the consultancy offices, six Counties (i.e. Bomi, Bong, Cape Mount, Margibi, Montserrado, and Nimba) Health Offices, and the host for the NDP workshop, the Pharmacy Division. Also, funding and technical assistance provided by the WHO for making of t his policy is very much appreciated.

Our gratitude goes to the Honorable Deputy Minister for Technical Services and Chief Medical Officer of Liberia, Dr. Nathaniel S. Bartee, for his regular coaching advice given us throughout the preparation of this policy; as well as to Dr. Peter S. Coleman, the Honorable Minister of Health and Social W elfare for contribution of his excellent foreword to this policy document.

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#### Acronyms

ACI	onyms	
1	ADB	: African Development Bank/Asian Development Bank
2	ADR	: Adverse Drug Reaction,
3	AIDAB	: Australian International Development Assistance Bureau
4	ATOD	: Alcohol, Tobacco and Other Drugs
5	CGMP	: Current Good Manufacturing Practice(s)
6	CHAL	: Christian Health Association of Liberia
7	CIDA	: Canadian International Development Agency
8	CMB	: Complementary Medicine Board
9	СР	: Chief Pharmacist
10	CPO	: County Pharmacy Office/Officer(s)
11	DANIDA	: Danish International Development Agency
12	DRA	: Drug Regulatory Authority
13	DSE	: German Foundation for International Development
14	EC	: European Commission
15	ECOWAS	: Economic Community of West African States
16	EDC	: Essential Drugs Concept
17	EDL	: Essential Drugs List
18	EDP	: Essential Drug Program/Policy
19	FDCB	: Food, Drugs, Cosmetics, and other Chemicals Board
20	GMP	: Good Manufacturing Practices
21	GOL	: Government of Liberia
22	GTZ	: German Agency for Technical Cooperation
23	IADB	: Inter-American Development Bank
24	IBRD	: International Bank for Reconstruction and Development (World Bank)
25	INCB	: International Narcotics Control Board
26	INN	: International Non-proprietary Name
27	LEDL	: Liberia Essential Drugs List
28	LNF	: Liberia National Formulary
29	MD	: Medical doctor
30	NDS	: National Drugs Service
31	NF	: National Formulary
32	NGO	: Non Governmental Organization
33	PA	: Physician Assistant
34	PBL	: Pharmacy Board of Liberia
35	PTC	: Pharmacy and Therapeutics Committee
36	QA	: Quality Assurance
37	QC	: Quality Control
38	RDF	: Revolving Drug Fund
39	RN	: Registered Nurse
40	RUD	: Rationale Use of Drug
41	SIDA	: Swedish International Development Authority
42	TRIPs	: Trade Related Intellectual Property Rights
43	UNDCP	: United Nations Drugs Control Program
44	UNDP	: United Nations Development Program
45	UNICEF	: United Nations Children's Fund
46	UNIDO	: United Nations Industrial Development Organization
47	UNO	: United Nations Organization

# 1.0 GOAL AND OBJECTIVE OF THE NATIONAL DRUG POLICY

#### **1.1** The Goal of the National Drug Policy

The goal of the National Drug policy (NDP) is to use available resources to develop pharmaceutical services to meet Liberia's requirements in the prevention, diagnosis and treatment of diseases by using efficacious, high quality, safe and cost-effective pharmaceutical products.

#### **1.2** Specific Objectives of the NDP

1.2.1 To ensure the constant availability of safe and effective drugs to all segments of the population;

1.2.2 To provide drugs through the government, private, and non-governmental sector at affordable prices;

1.2.3 To facilitate rational use of drugs through correct diagnosis, sound prescribing, good dispensing practices, and appropriate usage;

1.2.4 To ensure that the quality of drugs manufactured in Liberia and those imported into Liberia meet internationally accepted quality standards,

1.2.5 To encourage self-sufficiency through local manufacture of drugs of acceptable quality for consumption and export; and

1.2.6 To ensure the provision of drugs for veterinary use.

#### 2.0 DRUG AVAILABILITY

#### 2.1 Choice of Drugs and Drug Selection

Standard Treatment Guidelines, Essential Drugs List and formulary will be revised periodically to keep up with current trend of medical practice. Addition of drugs to the Essential Drugs List will be based on standard treatment guidelines. The essential drugs shall be those drugs that are affordable and effective, and can treat the majority of the ailments in the country.

#### 2.2 Generic Labeling

All labeling for both locally produced and imported pharmaceutical products will carry the generic (INN) International Non-proprietary name) name in letters at least two thirds the size of the brand name.

The Ministry of Health will undertake educational campaigns to promote use of products on the Essential Drugs List, to promote prescribing and dispensing by generic name, and to promote awareness of the essential drug concept. Separate campaigns will be aimed at the public and health professionals.

#### 2.3 Prescribing and Dispensing

Prescribers will be encouraged to prescribe by generic name and use the Essential Drugs

Concept.

At the dispensing level, a less expensive generic equivalent may be substituted, unless the drug product has no generic equivalent or is known to vary considerably amongst various sources. In such a case, the prescriber will indicate "do not substitute" on the prescription.

A prescriber who wishes to dispense will be required to obtain a dispensing license from the Pharmacy Board.

Over the counter (OTC) drugs will be made available through licensed outlets in approved packaging, carrying printed instructions for use as approved by the Drug Regulatory Authority (DRA)

The dispensed medicines shall be put in a package which shall bear the following information: name of the patient, name of the product, instructions for use and precautions, name and address of the facility from where the medicine is dispensed.

#### **2.4 Drug Donations**

Drug donated to and within Liberia shall comply with the "Liberian National Guidelines for Donation of Drugs and Medical Supplies".

#### 3.0 PUBLIC SECTOR DRUG SUPPLY

The GOL will make adequate provisions for foreign exchange for the procurement of essential drugs and medical supplies. The procurement of essential drugs for public health facilities will be accorded adequate budgetary provision and foreign exchange.

The Government shall address the issues of lack of better incentives for health workers, inadequate and poorly distributed health infrastructure, the lack of adequately trained manpower and logistics, which have tended to hamper the efficient management of drug supply system.

The operations of the National Drug Service shall be evaluated by the MOH&SW and other stakeholders, in order to ensure that it continues to meet the needs of the country as an autonomous, "not-profit" drug supply institution. The viability of its funding shall be considered.

The National Drug Service system shall strengthen the logistics of drug distribution to ensure the prompt, safe and efficient distribution of drugs and medical supplies from depots/stores to end users, in an effort to preserve the quality or product during transport.

The needed logistics for moving drugs from one point to another shall be provided to ensure equitable distribution at all levels of the health care delivery system.

#### 3.1 Essential Drugs List

Government shall continue to develop a clear drug selection policy based on the Essential Drugs Concept. The selection of pharmaceutical products will be in accordance with the Essential Drugs List of Liberia (EDL), which shall be updated regularly to meet the health needs of the population in line with the World Health Organization (WHO) Model List.

# 4.0 DRUG SUPPLY BY PRIVATE SECTOR AND NON-GOVERNMENTAL ORGANIZATION

The purpose of the procurement policy is to ensure the availability, on the market, of the necessary quality and quantity of drugs, which will meet the health needs of the majority of the population at the lowest possible prices.

The private sector and NGOs shall be encouraged to adopt the concept and practice of essential drugs.

In the procurement of drugs in the private sector, priority shall be given to drugs on the Liberian Essential Drugs List.

Restricted drugs like psycho tropic and narcotics and their precursors shall be imported with the prior approval of the DRA.

#### 4.1 Adoption of the Essential Drugs Concept

The selection of drugs in Liberia will be based on the Essential Drugs concept, and consistent with the prevalent disease patterns, taking into account the various service delivery levels.

#### 4.2 Procurement

The National Drug Service and, where possible, other drug supply agencies shall carry out procurement of drugs based on International Competitive Bidding, as well as limited tender systems in case of emergencies.

Drugs and medical supplies procured by the NDS shall comply with the registration requirement of the GOL, and shall be procured under the generic nomenclature (INN). These drugs shall be limited to those contained in the Liberian National List of Essential drugs.

#### **5.0 IMPORTATION AND EXPORTATION OF DRUGS**

Importation of all drugs for both human and veterinary use will be strictly limited to products registered through the Ministry of Health. Importation of pharmaceutical products will be approved in advance by the Ministry of Health and Social Welfare. Veterinary products must conform to Animal Disease Control provisions.

The importation of pharmaceuticals and pharmaceutical inputs (raw materials) will be considered for exemption from duty and Value Added Tax. For purposes of importation, duty exemptions and exemptions from Value Added Tax, family planning commodities such as condoms and intrauterine devices will be considered essential pharmaceutical products.

There will be adequate designated storage facility for drugs, including cold storage at all ports of entry. These facilities will have supportive services for pharmaceutical inspection purposes.

The Ministry of Health will maintain information on drug imports and local production to help determine the national drug consumption and requirements.

To facilitate stabilization of the prices, imports of pharmaceutical products will be financed through the official Central Bank Foreign Exchange allocations.

# 6.0 LOCAL PRODUCTION

Government shall promote development potentials for local production of essential drugs and medical supplies in Liberia. This should be the overall goal of increasing self-sufficiency and production of essential drugs and medical supplies in the country.

Government shall provide the conducive atmosphere for capital development in local production of essential drugs listed in the national Formulary.

The Government will promote the establishment of drug manufacturing plants in the country through private ventures.

Drug manufacturing plants should be inspected regularly to ensure compliance with the standards of Current Good Manufacturing Practices (CGMP), as required by the drug regulatory body in the country.

#### 6.1 Patents

The Laws and conventions governing patents on drug shall be reviewed, in order to ensure that the Liberian public is not disadvantaged from accessing essential drugs and medical supplies.

#### 7.0 PHARMACEUTICAL RESEARCH AND DEVELOPMENT

Government will identify and support research and development activities that will facilitate the accomplishment of the objectives of the National Drug Policy.

The Government of Liberia shall encourage research in plants of medicinal value, to ensure the provision of quality services in traditional medical practice.

The School of Pharmacy, Medical School, and especially LIBR, should initiate research in traditional medicine, and disseminate the information to the public.

- a) Identification of health condition that can be effectively treated by traditional medicine.
- b) Developing appropriate methodology and technology for identification, production and development of the traditional medicine, especially those related to plant products.
- c) Undertaking scientific research to evaluate clinical efficacy and the safety of medicinal plants. The active substances may be systematically identified and evaluated.

#### 8.0 DRUGS DISTRIBUTION, STORAGE AND MAINTENANCE

Appropriate measures shall be put into place to ensure that the quality of pharmaceutical products is maintained during storage. Guidelines on Good Warehousing Practices will be enforced, including the provision of stringent security against thefts and related actions.

The temperature, humidity and other relevant environmental conditions of the storage area should be maintained as required by Pharmacopoeia, or other standards accepted by the DRA.

The use of continuous uninterrupted energy supply like solar power should be considered in depots, especially those located in rural areas.

The use of procedural manual already developed to enhance the effective and efficient inventory control of drugs in storage shall be enforced in the NDS and other supply agencies, to ensure the continued availability of sufficient quantities of required drugs at all levels of the health care delivery system.

This procedural manual should be reviewed and revised periodically for the improvement and standardization of inventory control procedure.

A suitable computerized inventory control should be introduced where feasible.

Systematic practice and accurate procedures for the estimation and regular reporting of drug consumption at all levels shall be introduced and maintained, to enable correct estimation of national drug procurement needs.

# 9.0 LEGISLATIVE AND REGULATORY FRAMEWORK FOR CONTROL OF DRUGS AND PHARMACEUTICAL SERVICES

Government shall educate the public on the existing laws governing the practice of pharmacy, and that these laws shall be judiciously enforced. Moreover, some of the laws that need amendment shall be revised, to reflect the current realities in the practice of pharmacy and use of drugs in Liberia. The public health laws should be reviewed and revised, to include regulations and practices of traditional medicine. The Board of Complementary Medicine shall be autonomous and shall function under the Ministry of Health and Social Welfare.

The Board of Complementary Medicine shall be mandated to promulgate policies and enforce them. The policy should include but not be limited to: licensing/certification of practitioners and facilities providing services, importation of plant products of medicinal value, and setting up guidelines for practice/service.

#### 9.1 Regulatory Control

There is a need to harmonize and strengthen the existing provisions for the regulation and control of medicines and distribution channels in the country.

#### 9.2 Drug Control and Administration

The Pharmacy Board carries out the regulation of both medicines and pharmaceutical practitioners. In order to improve efficiency of regulation and control in the pharmaceutical sector, there shall be established an autonomous Drug Regulatory Authority which will be responsible for the regulation and control of medicines, medical supplies and cosmetics in Liberia.

The DRA shall establish a national drug laboratory for quality testing of drugs and related supplies. The DRA will be autonomous in its operations and shall be insulated from politics for effective regulatory functions. The DRA will collaborate with the relevant law enforcement agencies in the implementation of its functions where and when necessary. It shall be empowered to mobilize resources internally and externally for its operations.

The existing laws will be reviewed to support new DRA, whose functions shall include, but not limited

to, drug registration and licensing, post- marketing surveillance, pharmaceutical inspections, regulation and control of drug promotion and advertising.

# 9.3 Drug Registration

Procurement of drugs, including donations, will be limited to items registered for use in Liberia and also registered in the country of origin and sold on that market, except for certain drugs used for the treatment of specified tropical or other diseases.

All products imported in the country shall be covered by "Product Certificate" as recommended by WHO Certification Scheme for Pharmaceutical Products Moving in International Commerce.

Foreign and local suppliers of branded products will be required to label their product packages and containers with the generic name of the drug at least one-third size, and displayed adjacent to the trade name.

Only drug conforming to the accepted national requirements shall be registered and distributed in the country.

#### 9.4 Scheduling of Drugs

The various schedules of drugs provided under the current pharmaceutical legislation will be reviewed in line with the provisions of the NDP.

#### 95 Pharmaceutical Inspection

The DRA will establish a Pharmaceutical Inspection Unit, whose responsibilities will be, but not limited to, GMP inspections, the inspection of the distribution channels and post marketing surveillance. The Inspection Unit shall institute regular inspection of pharmaceutical plants and outlets in the country.

#### 9.6 Clinical Trials

The DRA shall be responsible for regulating and controlling drug clinical trials in Liberia.

#### 9.7 Traditional Medicine

The aim of the NDP on traditional medicine is to ensure that all substances used to treat patients are safe and effective.

Efforts shall be directed to improve all aspects of traditional medicines, which include coding of species of plants, indications, labeling, and duration of use.

The Ministry of Health and Social Welfare will strengthen the unit of complementary medicine within the Ministry, to enable it t6 function more efficiently. The Board of complementary medicine shall set regulations governing the practice of traditional medicine, as it relates to the use of plant products.

#### 9.8 Professional Associations and Professional Ethics

The Ministry of Health and Social Welfare will strengthen the regulation of pharmaceutical professionals through the Pharmacy Board. The interaction among the different bodies (MDs,

RNs, PAs, CMs, Pharmacists) within the health care delivery system will be encouraged. Professional bodies whose members provide pharmaceutical services will be encouraged to have their members adhere to ethical practice.

System for periodic dissemination of drug information for practitioners will be developed.

# 10.0 ECONOMIC STRATEGIES FOR DRUG FINANCING

#### **10.1 Revolving Drug Funds**

This policy is intended to address community health financing, so as to ensure the availability and accessibility to the public of safe, efficacious high quality drugs at the lowest possible price on self-sustainable basis.

Communities shall be encouraged to operate and control their organized community health committees and those committees shall be responsible for running their various RDF Schemes. The fee-for-services will be introduced in the health care delivery system at all levels, and part of the fees collected at each level shall remain in the facility, in order to fund the supply of essential drugs and medical supplies.

Government will explore various ways of standardizing prices of drugs on the market. This process will include the review of levies, options available under Trade Agreements, such as the Trade Related Intellectual Property Rights Agreements (TRIPS).

Government will promote competitive environment in the pharmaceutical sub-sector, in order to ensure that products are readily available at affordable process.

The role of Health Insurance Schemes will be evaluated as a strategy for public financing for essential drugs and medical supplies.

#### **10.2 Financing and Pricing of Drugs in the Private and Public Sectors**

Programs will be developed to provide for repayment for prescription drugs through the health insurance schemes. The private and public sectors will promote a viable and sustainable medical insurance scheme, as a mutual commitment to a comprehensive social welfare program.

Alternatives to the current pricing systems of medicines in the private sector will be explored, to find ways of making pharmaceuticals more affordable.

To encourage cost awareness, all drug distributors and manufactures will be required to provide their 'local wholesale price list to the Ministry of Health, according to an established timetable. The Ministry will publish these official prices at least once yearly and more often as appropriate. In addition, a mechanism will be established to exchange information with other countries on prices of individual pharmaceutical products.

Generic prescribing and substitution as well as selective drug registration should also control the usual drug costs paid by patients.

#### **11.0 RATIONAL USE OF DRUGS**

Government will ensure that the necessary programs for promoting rational use of drugs are developed

and implemented. These programmes will be geared towards prescribers, dispensers, and all health workers involved in the provision of pharmaceutical service delivery.

The curricula, as well as infrastructure of training institutions responsible for health workers will be developed and strengthened to improve the coverage of topics on rational use of drugs.

Programs for education of the public will be designed and implemented through workshops, media and other sources to enhance awareness of the public about the rational use of drugs.

Programs geared to the continuing education for health workers will be developed and implemented, to further strengthen the promotion of rational prescribing and dispensing of drugs.

Drug information centers will be established in major hospitals in order to provide objective, unbiased drug information service to both health workers as well as members of the public. User education will also be carried out as a means of improving compliance in medication regimen.

Sale and dispensing of drugs by non-professionals, and peddling of medicines will be curtailed through the enforcement of existing laws.

Programs to educate and inform the public on substances of abuse potential such as alcohol, narcotics and tobacco products will be developed.

#### **11.1 Prescription Practices**

All prescribers will be categorized, and the respective range of drugs that they will be expected to prescribe will be specified. Prescriptions must contain the following information: name and age of the patient, gender, weight, address, generic name, dosage, duration, dispensing institution and expiry date for all drugs on the prescription; and the full name and initials, qualifications/ designation, and signature of the prescribers.

#### **11.2 Treatment Guidelines**

Treatment guidelines for hospitals and outpatient health facilities in Liberia will be regularly updated and made available to government, private, mission and other health services. The use of these guidelines will be promoted through the use of the guidelines in pre-service teaching and inservice training.

The treatment guidelines will form the basis for revisions of the National Essential Drugs List, as well as for various training programs on rational drug use.

#### **11.3** Generic Prescribing

All procurement and prescribing of drugs in the public sector and all prescriber training in medical, paramedical, pharmacy, and other health profession schools will be based on the use of generic names. The use of generic names on prescriptions will also be encouraged for the private and NGO sectors.

#### **11.4 Education and Training**

All pharmacology and therapeutics training in medical, paramedical, pharmacy, veterinary, dental and nursing schools and all prescribing in teaching hospitals will be based on the Essential Drugs

### Concept.

The curricula of these institutions will include detailed information on the National Drug Policy, the concept of essential drugs, the Essential Drugs List, the use of the generic names, the drug supply system, and rational prescribing. Various licensing bodies shall establish Continuing Education Programs, attendance at which will be necessary for renewal of professional licenses, will be developed.

# **11.5 Pharmacy and Therapeutic Committees**

Each hospital must have Pharmacy and Therapeutics Committee (PTC) consisting of the Medical Superintendent/Medical Officer In-Charge (Chairperson), Pharmacist In Charge (Secretary), consultants and other members of the medical staff, Nursing Officer In-Charge, and other health professionals as appropriate. The PTC members will elect a vice-chairperson empowered to chair meetings in the absence of the chairperson. The PTC will be responsible for overseeing drug selection and formulary management, policies on prescription, drug utilization review, and policies on dispensing and administration of drugs. The PTC must approve all drugs available at the hospital. The PTC should also establish policies for promotional activities by drug company representatives and evaluate their promotional material.

# **11.6 Drug Information**

Strategies should be developed and implemented to ensure the provision of unbiased information on the handling and rational use of drugs.

The National Formulary and Drug Treatment Guidelines should be periodically revised, to provide essential information on the individual items incorporated, in order to serve as basis for the formulation of guidelines for rational prescribing, dispensing and use of drugs.

Guidelines and regulations shall be formulated as policy documents to ensure rational prescribing, dispensing and use of drugs.

#### **11.7 Drug Advertising and Promotion**

The DRA will regulate and control all forms of drug promotion and advertising, to ensure dissemination of objective and unbiased drug information.

# **12.0 QUALITY ASSURANCE**

Quality assurance is to ensure that pharmaceutical products meet all the established specifications and standards and that each drug reaching the patient is safe, effective and of an acceptable quality

# **12.1 National Quality Control Laboratory**

The DRA will establish and operate a national drug laboratory for the purpose of evaluating the standards of medicines in the Liberian market.

The GOL, through the Ministry of Health and Social Welfare, the Pharmacy Board, NDS and other relevant agents, shall be partners in the operation of the drug laboratory.

The Laboratory shall support the post-marketing surveillance programs of the DRA.

### **12.2 Good Manufacturing Practices**

All manufacturers will be required to adhere to internationally accepted standards for Current Good Manufacturing Practices (CGMP).

The location, architectural design and construction of a pharmaceutical factory will be subject to specified minimum requirements. Such requirements should be consistent with standards, which will meet criteria established by the DRA.

The DRA will establish criteria for personnel to man quality assurance and production sections of a pharmaceutical manufacturing facility.

Adherence to GMP and quality assurance policies will be enforced by the QA-GMP team in the Pharmacy Inspection Unit of the DRA, according to international guidelines.

#### **12.3 Certification Schemes on the Quality of Pharmaceuticals**

The WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce will form the basis for a national certification scheme for the import and export of pharmaceuticals. This will also cover any regionally adopted "Certification or Mutual Recognition Schemes".

# **13.0 HUMAN RESOURCES TRAINING AND DEVELOPMENT**

Government will ensure that qualified trained persons registered under the pharmacy laws of the land handle pharmaceuticals circulating in the country.

The training of pharmacists to undertake supervision of pharmaceutical services in the country will be encouraged. In this regard, Government shall intensify its support to the School of Pharmacy at the University of Liberia.

To support the management and control of pharmaceutical products in the country, intermediate pharmaceutical personnel (i.e., dispenser) shall be trained. In view of this, appropriate courses shall be designed ad incorporated in the curricula of health training institutions in the country.

In order to update and improve the pharmaceutical service in the country, continuing educational program shall be drawn up and implemented for pharmaceutical personnel in both the public and the private sectors.

The skills of practicing dispensers will be enhanced and their levels up-graded. The training of new dispensers will be resumed.

Post graduate training for pharmaceutical staff will be promoted.

#### 14.0 MONITORING AND EVALUATION

The GOL will establish the necessary and relevant mechanisms for monitoring and evaluating the performance of the National Drug Policy, to ensure success in the implementation of each and every aspect of the policy. Base-line surveys, mid-term evaluation and end of implementation period assessment of the program will be conducted.

# **15.0 INTERSECTORAL AND TECHNICAL COOPERATION**

The Government shall maximize inter-sectoral cooperation and collaboration, in order to achieve the overall goal of an efficient cost and self-sustaining pharmaceutical sector.

The Government shall actively pursue all relevant forms of technical cooperation, national and international, in order to ensure the efficient utilization of the available resources.

#### 16.0 GLOSSARY

- **1. acupuncture** a method of medical practice, traditional to most Asiatic nations, which is itself the treatment of illness, etc. by sticking needles into the patient's skin at various points.
- 2. **adverse drug reaction:** any other resultant effect seen (as the drug recipient's unexpected response) but which is not intended when a drug is employed for any one or any combination of the purposes of diagnosis, treatment, and prevention of a disease. This definition excludes the result of drug abuse and/or drug misuse and addiction.
- **3. allopathy:** treatment of a disease by use of remedies that produce effects that are opposite to those produced by the disease being treated. Today, loosely applied to the general practice of medicine, it is specifically the opposite of homeopathy (cf.)
- **4. alternative medicine:** a more ambiguous term though, this is the interchangeable form for complementary medicine.
- **5. amend:** to change(something that is, usually, in a written form) for improvement; **amended** (the past tense for amend).
- **6. amendment:** (a) change (usually in something written, especially a law, etc.).
- 7. **ayurveda:** a medical practice traditional to followers of the Hindu religious system, especially in India. It involves the combinations of herbs with rubbing essential oils whose active principles have not undergone any chemical variation. **ayurvedic** (adj.): pertaining to ayurveda; **ayurvedic medicine** or **ayurvedic product** (or, simply, **ayurvedic):** any medicinal agent prepared according to ayurveda.
- **8. brand** (adj.): maker's or new; **brand** (n.): a maker's name or trademark.
- **9. brand name** ( of a drug): the name of a drug which designates its formulation and most particularly its manufacturer and which thus distinguishes the manufacturer's products from those of competitive producers. It is also known as the proprietary, or trade, or trivial, or the unofficial name.
- **10. complementary medicine:** see alternative medicine and traditional or indigenous medicine. The word "complementary" connotes "additional to" the (orthodox) practice.
- **11. controlled drugs:** narcotic drugs and psychotropic drugs or substances regulated by provisions of national drug laws and international conventions.
- 12. controlled substance: same as controlled drugs and, in addition, may be a precursor

chemical.

- **13. cosmetic** (adj.): pertaining to a cosmetic product, orbeauty-enhancing and defectshiding; **cosmetic** (n.): any chemical product which, foreign to the body, is inert and which when brought into or applied onto the body imparts no physiologic change but rather brings about or enhances the body's beautification and its associated cleanliness (provided it is used in the rightful quantification, at the rightful application site, and does not contain a very harsh or toxic chemical). Cosmetics include toothpastes; lipsticks; substances or products such as soaps and other detergents; perfumes and colognes; and deodorants but not antiperspirants.
- **14. dispensary**: a place (usually of a treatment facility) whence medicines or drugs and related sundries are dispensed; also the pharmacy here.
- **15. dispense:** to give or prepare and give (especially a medicine) out; to deal out.
- **16. dispenser:** one who is trained and licensed or registered to dispense (medicines). Practically, one who, though not a (graduate) pharmacist, is trained to prepare and distribute, to a patient, a course of medication on the basis of either an oral or written prescription; to manage stocks and to maintain records of same of drugs and non-drug therapeutic items; and trained in the procurement of drugs and non-drug therapeutic items.
- **17. dispensing:** (v.) giving or dealing out ( especially a course of medicines); **dispensing** (n.): that area of pharmacist-training that embodies prescription-handling or prescription-filling, drug product distribution, including drug delivery and drug administration to the patient and drug management.
- **18. donor agency:** one that donates or one that gives to a fund. Here, it should be noted that the WHO is, however, not conventionally a donor agency.
- **19. dosage :** the dose of a medicine and the frequency of time it is given or is to be given over the total period of treatment, when spoken of together.
- **20. dosage form:** (of a drug) the form in which a drug substance is physically present and is administered. It may be a solid dosage form such as a capsule, tablet, pill, lozenge, suppository, or pessary, or a liquid dosage form such as ampoule or vial (i.e. both are injectable ), syrup, suspension, elixir, or semi-solid dosage form such as cream, lotion, ointment, emulsion, etc.
- **21. dose :** the amount of medicine that is to be taken at a moment.
- **22. drug** : any substance or mixture of substances which is conventionally intended for the diagnosis, treatment, alleviation or prevention of disease or disease symptoms in man or animal and may include vaccines and sera; allopathic, ayurvedic, homeopathic, and other traditional remedies such as merely herbal and other plants-derived medicines that are complementary to orthodox medicines.
- **23. drug information**: the drug plus the information that goes with it (as found on the package insert in its package or as labeled).
- 24. **drug information center**: a center for storage of drug information reference materials such as literature and other data bank.

- **25. drug management:** this is management as applied to the wise utilization of the resources relative to drugs (and this includes, inter alia, drug selection, quantification, procurement, storage, staffing and staff training) to achieve, conventionally, the desired results of the wise use of drugs, the availability or prevention of drug shortages or wastages, etc.
- **26.** drug product: same as (drug) dosage form.
- **27. drug regulatory authority:** the administrative structure or body responsible for licensing in matters of drugs and related issues of a country or state.
- **28. essential drugs:** drugs that satisfy the health needs of majority of a given population, including the income bracket, and are available at all times in adequate quantities and at all levels of the health care **delivery** system of (i.e. indispensable to the population) and the selection of which is based on the most **common** local diseases.
- **29. essential drugs program:** (of a population or country) a drug management program and strategy which comprises the selection of drugs based on primarily the most common morbidity pattern, and the formalization of a list of the selected drugs that are effective, safe, less expensive, or satisfy the health needs of the majority, and are of high quality; the quantification, procurement, and distribution of the drugs; rational use (including prescribing and dispensing of drugs and patient drug compliance); quality control and related legislative education-type health education; appropriate staffing and staff training; the needed physical and fiscal resources and an overall drug and/or pharmaceutical policy to guide the actors throughout the country or population.
- **30. generic** (adj.): pertaining to chemical kingship; **generic** (n.): also the drug substance as may be called not by its brand name.
- **31. generic equivalent** (of a drug): a drug substance having the same biologic equivalence (same as pharmacological efficacy) to another substance is said to be generically equivalent to it.
- **32. generic name** (of a drug): also known as the official name, or common name, or the nonproprietary name, of the drug substance, is the contracted form of the chemical name of the substance which has been rearranged for euphony (when pronounced) and for ease of recognition, and memory; and, as such, it refers to the form of the drug substance in which it is isolated or synthesized. In short, it is the official name of a drug regardless of the manufacturer; it is sometimes referred to as the INN, and it is the name recognized by the WHO.
- **33. GOL agency:** a ministry or public corporation or any other entity of the Government of Liberia.
- **34. GOL health care facility or institution:** a GOL hospital, health center or clinic, or health research facility.
- **35. herb:** a plant, most usually leaves-bearing, but with a fleshy stem and that is either of a creeping or climbing nature and is not or is below the taxonomic advancement of a shrub and more below that of a tree. NOTE: herb is not the same as an underground stem such as an onion bulb, potato tuber, etc.; **herbal:** pertaining to or derived from a herb.
- **36. homeopathy:** a system of medical practice based on the theory that certain diseases can be cured by given very dilute (i.e. small or weak)doses of drugs which in a healthy person would

produce symptoms like those of the disease being treated.

- **37. label** (v.): to mark on or write on (e.g. as on a medicine container); **label** (n.): the mark or writing so made on something or a parchment affixed on something (e.g. on a medicine container).
- **38. labeling** (n.): same as the written information (e.g. as to how a medicine is to be taken).
- **39. law** : a collection of rules according to which people live in or are governed in a country (qv. **statute:** the law made by a legislature; **regulation:** that made by a sectoral administration, e.g. a regulatory board); also called **legislation.**
- **40.** medical supply. a non-drug therapeutic item.
- **41. multiple drug therapy:** use of more than one drug to treat a disease at the same time; same as **polypharmacy**
- **42. narcotic:** a morphine-like drug that relieves pain and induces stupor.
- **43. nomenclature:** the art of naming; naming itself.
- **44. non-prescription drug:** same as over-the counter (OTC) drug; this is a drug with minimum side effect(s) and toxicity that it can be sold from licensed dealers without professional supervision and without prescription. Such a drug is suitable for self-medication for minor diseases and symptoms.
- **45. non-proprietary name :** (of a drug) same as **generic name** (cf./qv.).
- **46.** over-the counter(OTC) drug: see non-prescription drug.
- **47. parastatal:** an autonomous or semi autonomous agency (e.g. drug supply agency) that is constituted either under a sector (e.g. ministry ) of government or as an independent organization but with a board of directors from several government sectors, and whose primary client is government's (e.g. health) services.
- **48. pharmacy** (**n**.): a shop wherein medicines are sold conventionally under the superintendence of a licensed pharmacist; also a hospital dispensary. **pharmacy** (n.): as a profession, is that science that deals with the recognition and isolation of drug substances (in the case of plants-derived medicines); the synthesis of drugs (in the case of synthetic drugs); the compounding, storage, and dispensing of drugs; and also imparting of drug information to both the prescriber and the patient, etc.
- **49. pharmacist :** a holder of a degree or diploma in pharmacy from a recognized higher (usually a tertiary level) institution of learning and is registered or licensed to practice pharmacy.
- **50. pharmacist-auxiliary:** a pharmaceutical personnel other than and ranking below the status of a pharmacist (e.g. a pharmacy-technician otherwise called a dispenser; also a pharmacy aide or pharmacy assistant); **pharmacy-auxiliary:** a discipline belowthatof pharmacy-proper(e.g. dispensing, as a course).
- 51. Pharmacy drugs sale only: drugs that are authorized to be sold only in licensed and

registered pharmacies and without prescriptions.

- **52. pharmaceutical** (adj.): pertaining to pharmacy; **pharmaceutical** (n.): a pharmaceutical substance or product.
- **53. pharmaceutical personnel:** anyone licensed to practice any aspect of pharmacy proper or of sub-pharmacy (a pharmacist or a dispenser, respectively).
- **54. pharmaceutical product:** a pharmaceutical dosage form (i.e. the raw active ingredient made into a g<sub>b</sub> particular dosage form).
- **55. pharmaceutical substance:** the drug itself as the active ingredient.
- **56. poison:** a chemical preparation or substance defined by a national drug law as a poison (as a poison is legally defined based on its intent of use or mode of use).
- **57. polypharmacy:** see multiple drug therapy
- **58. precursor substance** (or, simply, **precursor**): a chemical substance used to process a narcotic or a psychotropic substance into a particular chemical form (e.g. hydrochloric acid, though not a drug on its **own**, **is** a precursor substance as it is used to process cocaine in the form cocaine hydrochloride which **is called** "crack". On the other hand a precursor may, sometimes on its own, be used as a drug (e.g. the bronchodilating anti-asthmatic, ephedrine, is used as a precursor for conversion to metamphetamine).
- **59. prescriber:** a licensed medical practitioner (e.g. a physician, a dentist) or a veterinarian.
- **60. prescription:** either an oral or written request, by a licensed prescriber, to the pharmacist or dispenser to prepare and give out, to a human or animal patient, a particular medicament in a given quantification.
- **61. quality** assurance(relative to pharmaceuticals): is a wide-ranging concept as well as process that covers all matters that individually or collectively influence the quality of a (pharmaceutical) product or substance. It is the totality of the arrangements or steps made with the object of ensuring that the pharmaceutical substances or products are of the quality required for their intended use.
- **62. quality control** (of pharmaceuticals): the measures taken including the setting of specifications, sampling, testing, and analytical clearance of raw materials, intermediates, packaging materials, and finished products to ensure that the finished product conforms with established specifications, identity, strength, purity, and other characteristics.
- **63. Rational use of drugs:** the appropriate use (i.e. prescribing and dispensing, including imparting of correct drug information to or counseling of the patient as to the use of her/his medication) of drugs for the right indications, in the right quantities, at the right time at affordable (i.e. less expensive) prices instead of use or prescribing of newer expensive ones.
- 64. **Regulations:** see law and statute.

- **65. Review** (v.): to go over or study again (often of a written work) without making correction(s); **review** (n.): the over-going of a work without necessary making corrections.
- **66. Revision:** a review or subsequent study or examination of a work corrections. **NOTE:** A REVISION is or can sometimes be used to mean an amendment.
- **67. Revolving drug fund:** a drug-financing scheme whereby or where drugs are sold at cost-pricing or, more realistically, cost price plus a mark-up and the revenue is used to replenish the drug stocks.
- **68.** Side effects (often said of a drug): the extra effect of a drug in addition to its desired therapeutic effect(s). Though many authorities reserve the term "unwanted effect" for this extra or additional effect-type of adverse drug effects, the side effect of a drug may generally be either beneficial or bad in terms of the drug recipient's response to it.
- **69.** Statute (legal): see law.
- **70.** Therapeutic (adj.): pertaining to treatment; therapeutic (n.): a medicinal agent or drug product (plural +s); therapeutics (n.): as a science or art, same as therapy which is the branch of medicine that deals with the treatment and cure of diseases, primarily with use of drugs.