LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

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Monrovia, Montserrado County
Republic of Liberia

POLICY ON LISTING AND IMPORTATION OF AMERICAN AND EUROPEAN PRODUCTS IN LIBERIA

Version 001

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STATEMENT FROM THE MANAGING DIRECTOR

As a National Regulatory Agency for medicines and health products, the Liberia Medicines and Health Products Regulatory Authority is responsible to ensure the efficacy, quality and safety of all medicines and health products that circulate on the Liberian market. Additionally, it is incumbent upon the Authority to adequately disseminate relevant information for public consumption, and create a working tool for utilization by the public.

Against this background, this policy has been developed to provide guidance for all imported American and European Products in Liberia.

I appreciate the contribution of the Quality Management System and the team of validators for their guidance in the development of the Policy on the Listing and Importation of American and European Products.

Hon. Luke L. Bawo
Managing Director
Liberia Medicines & Health Products Regulatory Authority (LMHRA)

LIST OF ABBREVIATIONS

API	Active pharmaceutical ingredient
BP	British Pharmacopoeia
CEPT	Certificate of Suitability
CPP	Certificate of Pharmaceutical Product
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practice
ICH	International Council for Harmonization
IVIVC	in vitro-in vivo correlation
JP	Japanese Pharmacopoeia
LMHRA	Liberia Medicines & Health Products Regulatory Authority
OTC	Over-the-counter
Ph.Eur.	European Pharmacopoeia
Ph.Int.	The International Pharmacopoeia
SmPC	Summary of Product Characteristics
SOP	Standard operating procedure
USP	United States Pharmacopeia
WHO	World Health Organization

GLOSSARY

The definitions provided below apply to the words and phrases used in this policy to facilitate interpretation of this policy:

Active pharmaceutical ingredient (API)

Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

American and European (A&E)

Products are medicines or health products that are not readily available on the Liberian market but are needed to meet the varying, unique individual health needs of patients and clients within the community.

Applicant

The person or entity who submits an application for product registration to the Authority is responsible for all the product information.

Authorized local agent (Representative)/Marketing Authorization Holder (MAH)

Any pharmaceutical company or Pharmacist established within a country or jurisdiction who has received a mandate from the manufacturer to act on his behalf for specified tasks with regard to the manufacturer's obligations under legislation of the medicine and other regulatory guidance's issued by the Authority.

Dosage Form

Formulation of an active ingredient(s) so that it can be administered to a patient in specified quantity/strength, e.g., tablets, capsules, injection solution, syrups, ointments, suppositories, etc. "Pharmaceutical Form" and "Finished Product" are synonymous to "Dosage Form.

Generic Products

The term generic product means a pharmaceutical product, usually intended to be interchangeable with the innovator product, which is usually manufactured without a licence from the innovator company and marketed after expiry of the patent or other exclusivity rights.

Labeling

Includes any legend, word, or mark attached to, included in, belonging to, or accompanying any drug including: 1) the immediate container label; 2) cartons, wrappers, and similar items; 3) information materials, such as instructional brochures and package inserts.

All operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to completion of the finished product.

Packaging material

Any material, including printed material, employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

Packaging

All operations, including filling and labeling, that a bulk product has to undergo in order to become a finished product. Sterile filling would not normally be regarded as part of packaging, the bulk product being the filled, but not the finally packaged, primary container.

Standard operating procedure (SOP)

An authorized written procedure giving instructions for performing operations not necessarily specific to a given product or material but of a more general nature (e.g., equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.

Specification

A document describing in detail the requirements with which the products or materials used or obtained during manufacture have to conform. Specifications serve as a basis for quality evaluation.

Stability

The ability of an active ingredient or a drug product to retain its properties within specified limits throughout its shelf-life. The chemical, physical, microbiological, and biopharmaceutical aspects of stability must be considered.

BACKGROUND

Medication across the worlds are procured and imported based on consumption data. That is how much of the specific commodity can be consumed in a particular location at a specified timeframe. Hence, not every essential medication is needed on a large scale in a specific region – this could be tailored towards diseases prevalence, low consumption rate, the economic factor (low purchasing power of the people), etc. Therefore, the need to import said low consuming but highly essential medications on the low scale basis to maintain their availability in the commerce of Liberia is inevitable.

American and European products are therefore considered as essentially imported products that are purchased from the American and European markets and venders in a small quantity to be sold at the retailed level on the Liberian market. Largely, these products are produce by large America and European manufacturing companies. These manufacturing companies are hardly likely to sell to individuals or give their dossiers to an individual person(s) for product registration.

Since there is a serious need for the availability of products in this category on the Liberian market, the LMHRA has promulgated this policy to regulate the procedures involved in the listing and importation of American and European products.

1.0 INTRODUCTION

The regulation of medicines and related health products in Liberia is governed by the provisions and requirements of the Liberia Medicines and Health Products Regulatory Authority (LMHRA) Act, 2010.

The law requires that all medicines manufactured, imported or exported, distributed, or sold in Liberia should be of acceptable quality, safe and efficacious. The process of medicines registration forms an important basis for evaluating and assuring that medicines and health products are of good quality and safe. Mindful of the need to increase access to quality medicines and to promote and protect public health by developing regulatory systems that satisfy minimum regulatory capacity, the Liberia Medicines and Health Products Regulatory Authority has adopted the fast-track procedures for listing American and European products and to restore transparency and credibility in the importation of A & E products by human in Liberia.

Objective

This policy is intended to provide guidance to applicants on how American and European products are processed at LMHRA and the requirements for the importation of said products in Liberia.

LEGAL BASIS

In pursuance of Part IV Section 2a and Section 2b of the Act to Establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010 which says the authority shall conduct registration of medicines and health products; Issue licenses or permits for premises and personnel to engage in the manufacture, import, export, transit into or out of the Republic of Liberia, supply, storage, distribution, or sale of medicines and health products, excluding retail pharmaceutical outlets.

2.0 Application:

2.1 Application shall be open to all registered pharmacies owned and operated under the license of a registered Pharmacist with valid Licenses issue by the Pharmacy Board of Liberia and has a valid importer's license to import pharmaceuticals in Liberia.

2.3 Applications from Development Partners, Multinationals, Ministries, Departments, and Agencies can be processed under this scheme in special circumstances or in line with existance guidelines for medicines registration and evaluation.

2.4 Applications from Hospitals and Clinics licensed by the Medical and Dental Council of Liberia and with valid importers License issue by LMHRA will also be considered.

2.5 All products are to be registered and Evaluated per the registration guidelines however Products that qualify to be treated under the American and European Products Scheme are those which are needed for the treatment of critical health conditions for which there are no local capacity to meet these needs or with low market value.

2.6 The maximum pack size of American and European Products to be imported shall be two hundred and fifty (250) units. More besides, importation of said products shall not exceed three times per annual.

2.7 Only brands or generics that are not already registered will be permitted. However, any company wishing to import small quantities of any already registered brands or generics must obtain a "no objection letter" from the Market Authorization Holder (MAH).

2.8 The under listed products DO NOT qualify for the American and European products:

i. Products for which there is local manufacturing capacity

ii. Products for which there are safety concerns.

iv. Products on the Ministry of Health of Liberia and LMHRA Import Prohibition.

vi. Any product that may be affected by Regulatory Directives

2.9 Where there are Narcotics, Psychotropic substances, and Controlled Drugs, Authorization to import and clear such drugs must be obtained from the Directorate of Pharmaceutical Services of the Ministry of Health of Liberia and the Liberia Medicines and Health Products Regulatory Authority (LMHRA).

2.10 Every product submitted for listing as American and European Product shall conform to the Regulation on Labeling of medicines and health products **(Document Code: DOC-REG-010) and shall be subjected to preliminary screening before authorization**.

2.11 All listed A & E products should be subject to post-market surveillance. Applicants are required to report adverse drug reactions and maintain a functional pharmacovigilance system and database, which should be shared periodically with the LMHRA.

3.0 Source of American and European Products:

3.1 The products shall be sourced from any of the under listed manufacturing facilities qualify under this scheme:

i. Facilities situated in World Health Organization-Listed Authorities (WLA) member countries.

ii. Facilities are situated in the pharmaceutical Inspection Co-operation Scheme (PIC/S) member countries.

iii. Facilities situated under the European Medicines Agency (EMA)

3.2 The Authority would consider medical products coming from WLA or PIC/S member countries if the products are World Health Organization (WHO) prequalified, and the applicant can provide justifications using data, e.g., WHO reference number, WHO Public Assessment Report (WHOPAR), and WHO Public Inspection Report (WHOPIR).

4.0 Documentation:

4.1 The application letter addressed to the:

Managing Director, Liberia Medicines and Health Products Regulatory Authority (LMHRA), Mamba point, Sekou Toure Avenue, 2nd & 3rd Floor Clay Building, Monrovia, Liberia

4.2 MS Excel document (soft copy) that includes a list of drugs with the following column headers:

1. Product/Brand Name

2. Active Ingredient and Strength

3. Pack Size

5. Quantity

6. Manufacturer Name and Address

7. Manufacturer's Country of Origin.

8. Valid Liberia Pharmacist License.

9. Valid Premises/Hospital/Clinic License, if applicable.

10. Any other document that the Agency may request

5.0 Application Processing Fees

5.1 The Processing Fees charged for the American and European Products Scheme shall be three Hundred United States ($300.00USD) per product however critical life-saving medicines, orphan products with no commercial value can be listed and said approval must be channel from a committee of three members of the TCDE through the office the managing director for final approval.

i. Permit or the listing for American and European Products shall be valid for one (1) year from the date of listing.

ii. Listed American and European Products authorized shall only be imported in the approved quantity and shall be only for retailed purposes NOT to be wholesale.

iii. Any American and European products imported into the country without the necessary permits shall be considered as substandard and falsified medicines and shall be confiscated and subjected to procedures for unauthorized importation.

iv. All approved applications shall be immediately fast track for listing and details registered on the American and European Products Listing Registry as:

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6.0 OFFENSES AND PENALTIES

- Any person(s), institution(s), Corporate Entity(ies), their Designees or legal representatives who violates any provision of this policy, shall be liable to regulatory fines ranging from One Thousand United States Dollars to Five Thousand United States Dollars (US$1,000.00 - US$5,000.00).

The ***Policy on Listing and Importation of American and European products in Liberia is Hereby Promulgated and Approved by the Managing Director on this 6th Day of May A. D. 2026.***



Hon. Luke L Bawo
Managing Director / LMHRA