



**LIBERIA MEDICINES & HEALTH
PRODUCTS REGULATORY AUTHORITY
(LMHRA)**

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**REGULATIONS ON ADVERTISEMENT
OF MEDICINES AND HEALTH
PRODUCTS**



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DECLARATION

This Regulation, made in fulfilment of PART V, Section 7 of the Liberia Medicines and Health Products Regulatory Authority Act of 2010, which confers upon the Authority the responsibility of regulating medicines and health products within the Republic of Liberia. The Management, with approval of the Board of Directors hereby promulgate this regulation designed for advertisement of medicines and health products this **6th** day of **January**, 2022.

CHAPTER I PRELIMINARY

Section 1: Title

This Regulation, cited as the Authority’s Regulation on Advertisement of Medicines and Health Products.

Section 2: Application and Scope

This regulation shall apply to Advertisement of all over the counter (OTC) medicines and health products that are manufactured, imported, distributed, stored, sold and used in Liberia.

Section 3: Purpose

The purpose of this Regulation is to provide a legal framework for the effective and efficient regulation of advertisement of OTC medicines and health products.

Section 4. Definitions

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

- “Act” means the Liberia Medicines and Health Products Regulatory Authority Act;
- “Authority” means the Liberia Medicines and Health Products Regulatory Authority;
- “Drug” means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or for improving physiological functions, or for agricultural or industrial purposes
- “Recall” means an action executed by a manufacturer or mandated by the regulatory body at any time to remove a defective or harmful medicines or health products from the market.

CHAPTER II REQUIREMENTS FOR ADVERTISEMENT

Section 1: Guiding Principles

The advertisement of OTC medicines and health products shall be done in accordance with this regulation to ensure the health and safety of all people within Liberia.

Section 2: Address for Advertisement Application

All applications for advertisement of medicines and health products must be made to the following address:

**The Managing Director
Liberia Medicines and Health Products Regulatory Authority (LMHRA)
P.O. Box 1994
1000 Monrovia, 10 Liberia**

Section 3: Filing of Application

The Authority requires that only marketing authorization holder (MAH) or the person authorized by the MAH can file an application for advertisement with the Authority.

Section 4: Requirements for Application

The application for advertisement of medicines and health products must be accompanied by:

- a. A copy of product registration certificate;
- b. A copy of advertisement (story sketch/story board/artwork) for radio, TV or billboards;
- c. Copy of payment receipt for non-refundable application fee for advertisement.

Section 5: Review of Application

The Authority shall review the application within 15 working days from the day the application was received. The Authority may decide to approve, defer or reject after assessment. The result of the assessment shall be communicated in writing to the MAH within seven (7) working days when a decision is reached.

Section 6: Deferment and Extension of Application

Application shall be deferred if the Authority needs additional information. In this case, the applicant is required to provide said information within fourteen (14) working days. Failure on the part of the applicant to provide the needed information or request for an extension within the stipulated fourteen (14) working days, the application shall be considered nullified. Approval of request for extension is at the discretion of the Authority.

Section 7: Validity and Revocation

When an advertisement is approved, it is valid for one (1) year from the date of approval. In accordance with Part V Section 6 of the LMHRA Act of 2010, the Authority can revoke approval of the advertisement based on new evidence concerning the product's quality, safety and efficacy or any other issues of public health and safety.

Section 8: Notification and Approval for Change

Posting of an approval change on the advertisement is subject to Authority's approval. The MAH must notify and obtain approval from the Authority. In the case where the MAH fails to notify or obtain approval from the Authority, the advertisement that has been altered after approval shall be nullified and attract sanction(s).

Section 9: Application for Reconsideration

The MAH may file an application with the Authority for reconsideration in the event an application was previously denied.

Section 10: Joint and Several Liability

In the event of putting up an advertisement not approved by the Authority, the MAH/representative, sponsor, advertising agent and the media organization shall be jointly and severally liable.

Section 11: Misleading Advertisement

A person or media institution must not advertise a medicine or health product that:

1. is false and misleading or present a deceptive information directly or by implication on the quality, composition, safety or efficacy of a product;
2. is not registered and approved by the Authority;
3. includes a statement by scientists or health professionals or well-known personalities or organizations recommending the use of a particular product to the detriment of health and safety;
4. duplicates advert contents (general layout, text, slogans or visual presentation or devices) of other companies;
5. targets children, pregnant woman or lactating mothers;
6. includes price competition;
7. offers gifts, free samples, refund of money or other inducements to attract consumers;
8. contains testimonials or purported testimonials about the use of the medicines or health products;
9. creates an unreasonable expectation of beneficial treatment;
10. contains therapeutic guarantees;
11. creates an erroneous impression regarding product safety.

Section 12: Requirements for Advertisements

All advertisements must:

- a. clearly communicate the product indication as stated in the marketing authorization. At least one indication/ recommended use must be included. For products with multiple medicinal ingredients that have been authorized to relieve multiple symptoms of a condition, at least one symptom per medicinal ingredient must be presented in the advertisement. However, it is acceptable to give prominence to one symptom;
- b. contain only one product that can be advertised per script. The authority shall not allow more than one product to be advertised on a single script. Each script shall be considered as a separate advertisement;

- c. be accurate, truthful, up-to-date, complete in terms of information, balance, and must clearly communicate the intended use of the product in accordance with the marketing authorization;
- d. advertise their products only and refrain from directly or indirectly disparaging any product of a competitor in their advert;
- e. comply with existing regulation for the treatment/ management of disease conditions;
- f. clearly advise the consumer on any age restrictions and special precautions and the need to seek medical attention should the symptoms persist after 48 hours.

Section 13: Specific Requirements for Over-the-Counter (OTC) Medicines and Health Products

A person or media must not advertise an OTC medicine or health product that:

- 1. Supposes that other treatments from any competitor are not good.
- 2. Supposes treatment or prevention of the following diseases or conditions:
 - a. Sexually transmitted diseases: Amenorrhoea, gonorrhoea, HIV-AIDS, syphilis, or chancroid (soft chancre) in any of their forms, and other sexually transmitted infections, habits associated with sexual indulgence, or of any ailment associated with those habits; or the restoration or stimulation of the sexual functions;
 - b. The prevention, relief or cure of blindness, Bright's disease, schistosomiasis, and cancer malignancies.
 - c. Only Over the Counter (OTC) Medicines must be advertised.

Section 14: Specific Requirements for Pregnant Women and Lactating Mothers

All advertisements of medicines and health products that may be used by pregnant women and lactating mothers shall state any known side effects of the medicine on the pregnant woman, fetus and infant.

CHAPTER III: OFFENSES AND PENALTIES

- I.* Any person(s), Business or Media Group, Corporate Entity (ies), their designees or legal representatives, who advertises a product(s) not approved by the Authority, as indicated in this regulation, the MAH/representative, sponsor, advertising agent and the Media Group shall be jointly and severally liable for any damages the said may caused to consumers and competitors.

This Regulation shall take effect immediately upon the approval of the chairman of the Board of Directors.

A Regulation for Advertisement of Medicines and Health Products is Hereby Promulgated and Submitted for Approval to the Board of Directors on This 6th Day of January A. D. 2022 by the Managing Director of the Authority.



Pharm. Keturah C. Smith-Chineh
Managing Director / LMHRA

A Regulation for Advertisement of Medicines and Health Products is Hereby Submitted to the Chairman of the Board of Directors for Approval.

Approved This 11th Day of February A. D. 2022



Prof. Hasipha C. Tarpeh
Chairman / Board of Directors