LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

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REGULATIONS FOR THE REGISTRATION 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 the registration of medicines and health products this **6th** day of **January**, 2022.

CHAPTER I PRELIMINARY

Section 1: Title

This regulation shall be cited as the Authority Regulation Governing the Registration of Medicines and Health Products and shall come into operation on the date of publication.

Section 2: Application and Scope

This regulation shall apply to all medicines and health products intended to be registered in Liberia.

Section 3: Purpose

The purpose of this Regulation is to provide a legal framework to ensure effective and efficient regulation of the registration of all medicines and health products, and to provide an open, transparent and non-discriminatory process for the registration of all 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 of 2010.

"**Active pharmaceutical ingredient**"means a substance or compound that is used in the manufacture of a pharmaceutical product as a therapeutically active compound (ingredient);

"**Applicant**" means the person by, or on whose behalf, an application for, an update or amendment to an existing registration, is made. After the product is registered, the applicant shall be the "Marketing Authorization Holder" (MAH).

"**Appropriate fee**" means the fee prescribed in Regulation as fees for the registration of medicines and health products and other related services that are Applicable to the Authority.

"**Approval**" means official consent by the Authority as an acceptable Standard;

"**Batch Manufacturing Record**" or its acronym "BMR" means all documents associated with the manufacture of a batch of bulk product or finished medicines and product;

"**Batch number**" or "**Lot number**" means a unique number or combination of numbers or cyphers allocated to a lot or a batch by the manufacturer;

"**Bioequivalence**" means the absence of a significant difference in the bioavailability between two pharmaceutically equivalent products under similar conditions in an appropriately designed study;

"**Common Technical Document''** (CTD) is an internationally agreed upon format required by regulatory authorities for well-structured dossier applications for the registrations of medicines

"**Composition**" means the ingredients of which the product consists, proportions, degree of strength, quality and purity in which those ingredients are contained;

"**Country of origin**" means a country in which the product has been manufactured;

"**Generic product**" means a product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference product, and whose bioequivalence with the reference product has been demonstrated by appropriate bioavailability studies;

"**Good Manufacturing Practice**" or its acronym "GMP" is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Authority;

"**Label**" means any tag, brand, mark, pictorial or other descriptive matter, written, printed stenciled, marked, embossed or impressed on or attached to a container of any product;

"**Manufacture**" means all operations that involve preparation, processing, filling transforming, packaging, and repackaging and labeling of products;

"**Manufacturer**" means a person or a firm that is engaged in the production of medicine and health products;

"**Recognized Pharmacopeia**"	means current version of, British Pharmacopeia, United States Pharmacopeia, European Pharmacopeia, Japanese Pharmacopeia and International Pharmacopeia, Indian Pharmacopeia, Chinese Pharmacopeia or approved National Pharmacopeia;
"**Registration Certificate**"	means a document for official approval of a product for circulation in the market;
"**Marketing Authorization**"	means an official approval of the product to be marketed or distributed in the country;
"Shelf Life"	in relation to any batch of a medicine, means the period up to which a medicine in that batch will retain the potency and properties stated on the label as fixed by the Liberia Medicines and Health Products Regulatory Authority
"**Site Master File**"	means a document prepared by the manufacturer containing specific and factual good manufacturing practice information about the production and/or control of pharmaceutical manufacturing operations carried out at a named site(s).
''Substantial Evidence''	means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereto.
"**Marketing Authorization Holder**"	means a person(s) or instition(s) that hold(s) an official approval of the product to be marketed or distributed in Liberia;

CHAPTER II REGISTRATION OF MEDICINES AND HEALTH PRODUCTS

Section 1: Application for the registration of medicine and health products

1. An application for registration of a medicine or health product must be made and submitted in electronic copies and on a USB drive and must be accompanied by the following:
   a. cover letter;
   b. dully filled in application form
   c. dossier in the **Common Technical Document (CTD)** format
   d. the appropriate non-refundable application fees for registration of products in applicable country as described in the fee schedule
2. All applications and supporting documents must be in the English Language
3. A separate and complete application for registration of medicine and health products must be submitted for each product.
4. Medicine and health product with different active ingredients, strengths, dosage forms, site of manufacture or proprietary names, must for the purposes of this Regulation be considered to be different products and the same shall require separate applications.
5. Notwithstanding the requirement of count 4, all parenteral preparations in different pack sizes shall require separate applications.

Section 2: Authenticity of Documents

1. All documents submitted must be authentic bearing a signature and seal attesting that it is genuine and official.
2. The Authority shall reject an application for the registration of a medicine or health product if the documents are not authentic or lack integrity of data.

Section 3: Accountability of the Applicant and Marketing Authorization Holder

1. The applicant must be accountable for all information supplied in support of his application for registration of the product and variations thereof.
2. The marketing authorization holder must be accountable for the following:
   a. manufacturing the product in compliance with the specifications approved according to provisions of this Regulation;

b. updating, when necessary, summary of product characteristics and package inserts for the purpose of enabling a correct and safe use of the product;
c. communicating the variations to the Authority within the framework of the relevant provisions of this regulation;
d. providing responses to the issues requested by the Authority, in relation to a registered product;
e. carrying out Pharmacovigilance to ensure the safety of the product in the market and provide updated reports to the Authority;
f. ensuring that the product continues to comply with the requirements prescribed in the Law and this Regulation including payment of annual retention fees prescribed in the current fee schedule;
g. ensuring that retention fees are paid immediately upon approval.

Section 4: **Safe custody and confidentiality of information**

1. The Authority shall ensure safe custody of information related to the registration of products submitted by applicants and marketing authorization holders.
2. All information submitted shall be treated as confidential and shall not be disclosed to any third party without a written consent of the applicant or marketing authorization holder.

Section 5: **Evaluation of products**

1. The Authority, upon acceptance of the application, shall cause the same to be evaluated to assess compliance with safety, quality and efficacy requirements.
2. The Authority may, during the evaluation of the product, require the applicant to submit additional samples, documents, information, data or clarification as the case may be.
3. When the Authority requires additional samples, documents, information, data and/or clarification, the processing of the application must not proceed until the applicant addresses the queries.
4. When the applicant fails to address queries within the period of six (6) months for Regular Registration and three (3) months for Fast Track Registration from the date of official request, the application shall be considered rejected.

5. An application rejected shall not be considered for registration. Applicant shall be required to submit a new application as per the requirements of this Regulation.
6. As a prerequisite to evaluation, the Authority shall, as it may deemed necessary, conduct on-site inspection to confirm current Good Manufacturing Practice (cGMP) status of the manuafcturing company.

Section 6: Registration of products

1. Following the evaluation of an application, the team shall present the outcome and recommendations to the Managing Director.
2. Upon receiving the recommendations of the evaluation team, the Managing Director shall submit same to the Expert Committee.
3. After review of the recommendation received, the Expert Committee shall submit its decision to the Managing Director for consideration.
4. If approval issued is for provisional registration, the conditions which need to be fulfilled by the marketing authorization holder to acquire full registration must be met within 30 days as of notification.
5. Upon approval of registration for a product, the Authority shall issue a Certificate of Registration and maintain a registry of the product;
6. The Authority shall regularly publish a list of registered products.

Section 7: **Validity of Registration**

1. A Certificate of Registration issued under chapter III section 6 count 5, of this regulation, shall be valid for a period of three years from the date of issuance and may thereafter be renewed.

Section 8: Application for Variation of a Registered Product

1. Any variation to a registered product must be notified to the Authority through an application in the approved format as stipulated in a guidelines for registration.
2. An application for variation must be submitted as per the requirements set out in a Guidelines for Variation of medicines and health products in force at the time of submission.
3. A distinction shall be made between major and minor variations in accordance with the Guidelines and there shall be a distinction in the application fees.

Section 9: Retention of Product on the Registry

1. Every marketing authorization holder must, in addition to the fees related to the registration of each product, pay retention fees pursuant to Chapter III, section 7, count 1 of this regulation.

Section 10: **Application for Renewal of Registration**

1. Application for renewal of registration must be made to the Authority at least ninety (90) days prior to its expiry by completion of the prescribed application form.

Section 11: **Suspension and Revocation of Registration**

1. The Authority may suspend and revoke registration of a product based on the following:
   a. The marketing authorization holder has contravened any provision of any part of the Authority's Act of 2010 and any regulation;

Section 12: Notice of Suspension and Revocation of Registration

1. All suspensions and revocations must be effected upon a written notice thereof.
2. A notice of suspension and revocation of registration of a product must:
   a. state the reason(s) for suspension and any corrective action required to be taken and the time within which it must be taken;
   b. require the marketing authorization holder to show cause as to why the suspension should not be effected.

Section 13: **Restoration of Registration**

1. Pursuant to the provision of chapter III section 12, the Authority shall reinstate the registration of a product upon satisfaction of the condition(s) giving rise to the suspension or revocation of registration.

Section 14: **Denial to Grant Marketing Authorization**

1. The Authority shall deny to grant marketing authorization of a product if:
   a. the method(s) used in, and the facilities and controls used for the manufacturing, processing, and packaging of such medicine and

health product are inadequate to preserve their identity, strength, quality, and purity; or

2. Pursuant to the provision of chapter III, section 15 count 1, where the Authority denies to grant registration of a product, the Managing Director shall inform the applicant in writing of such decision and the reasons thereof.
3. The denial of a marketing authorization shall constitute a prohibition on placing the product on the market.
4. The information about all denials and the reasons for such denial shall be made publicly accessible.

CHAPTER III RESTRICTION OF UNREGISTERED MEDICINES AND HEALTH PRODUCTS

Section 1: No person must manufacture for sale, distribution, offer, import or export medicines and health products by either wholesale or retail unless it is in accordance with the provisions of this Regulation.

Section 2: Notwithstanding the provision of section 1 of this chapter, this regulation shall not apply to-

i. any medicines or health products prepared in a pharmacy and is done by or under the supervision of a pharmacist in accordance with a prescription given by a medical practitioner, dentist or a veterinarian;
ii. any product prepared in a hospital pharmacy in accordance with the formulas of a pharmacopoeia, and intended to be supplied directly to patients served by the concerned pharmacy and commonly referred to as the official formula;
iii. medicines and health products intended to be used in research and development studies, without prejudice to the provisions of the Regulations on clinical trials in force;
iv. any medicines and health products prepared by a medical practitioner or dentist at the request of another medical practitioner or dentist for administration to a particular patient;
v. any medicines and health products prepared by a veterinarian specially for administration to a particular animal which is under his care without prejudice to the provisions of the Regulations on clinical trials in force;
vi. any medicines and health products prepared by a veterinarian at the request of another veterinarian for administration to a particular animal or group of animals under the care of that other veterinarian;
vii. any medicines and health products prepared and stocked in a hospital pharmacy by or under the supervision of a pharmacist with the view to dispensing;

Section 3: Any person who imports or manufactures for distribution, wholesale, retail, offer, or export of medicines and health products must be duly bound and held liable for any harm.

CHAPTER IV SPECIAL PROVISIONS

Section 1: Appeals and Review

1. Any person(s) aggrieved by a decision of the Authority may appeal to the Authority for review of a decision showing grounds for dissatisfaction within sixty (60) days from the date of notice.
2. The Authority shall, within 45 days from the date of receiving an appeal, review, reject or vary with its own decision.
3. Notwithstanding the provision of Chapter V, section 1, count 1 the applicant shall not be barred from appealing to the Authority's Board of Directors without applying to the Authority for review.
4. If a person is dissatisfied with the decision after review, he/she may appeal to the Board of Directors whose decision shall be final.

CHAPTER V OFFENSES AND PENALTIES

ADMINISTRATIVE SANCTIONS

In keeping with Part VIII, Section 1, 2 & 3 of the Authority Act of 2010, the following measures shall apply:

1. Any person(s), institution(s), Corporate Entity(ies), their Designees or legal representatives found in violation of provisions of chapter II section 1 shall be liable to pay a fine in the range of Two- Five Thousand United States Dollars (US $2,000- 5,000).

2. When it is established that the documents submitted to obtain registration are not authentic in keeping with Chapter III Section 1,2,3 of this regulation, the person(s), institution(s), Corporate Entity(ies), their Designees or legal representatives submitting said documents shall pay a fine of not more than Five Thousand United States Dollars (US $5,000).

CHAPTER VII SCHEDULES

Section 1 Application Form for Registration of Products

APPLICATION FORM FOR REGISTRATION OF A PRODUCT

TYPE OF APPLICATION – HUMAN, BIOLOGICAL OR VETERINARY PRODUCT			
MODULE 1: ADMINISTRATIVE INFORMATION			
SECTION 1: PARTICULARS OF THE PRODUCT			
1.0 Attach a cover letter			
1.1 Table of content of the application (MODULE 1-5)			
1.2 Application Information			
1.2.1	**Trade Name/Proprietary of the product**		
1.2.2	**Approved/International Non-proprietary Name (INN)/Generic name of the Active Pharmaceutical Ingredient (API)**		
1.2.3	**Dosage form and route of administration of the product:**		
1.2.4	**Strength of API per unit dosage of the product**		
1.2.4.1	Dosage form of the product:		
1.2.4.2	Route*(s)* of administration		
1.2.5	**Commercial presentation of the product:**		
1.2.6		**Nature and content of container**	
1.2.7		**Description of the product**	
1.2.8		**Country of Origin**	
1.2.9		**Category of distribution**	
1.2.9.1		POM (Prescription only medicine)	
1.2.9.2		P (Pharmacist initiated medicine)	

1.2.9.3		OTC (Over-the-counter medicine)	
1.2.9.4		**VETERINARY DRUGS**	
1.2.9.4.1		Veterinary Medicines (VM) Prescription	
1.2.9.4.2		Veterinary Medicines (General Dealer) – (V.M.G.D)	
1.2.10		**Pharmacological classification and indication**	
1.2.10.1		Pharmacological classification	
1.2.10.2		Indication	

1.2.11	**Proposed shelf life (in months) and storage conditions:**	
1.2.11.1	Proposed shelf life:	
1.2.11.2	Proposed shelf life (after reconstitution or dilution):	
1.2.11.3	Proposed storage conditions:	
1.2.11.4	Proposed storage conditions (after reconstitution or dilution):	

1.2.12 Name and address of Applicant

(Company) Name:

Address:

Country:

Telephone:

Telefax:

E-Mail:

1.2.13	**Name(s) and complete address (es) of the Manufacturer(s)**
1.2.13.1	**Name(s) and complete address(es) of the manufacturer(s) of the finished pharmaceutical product (FPP), including the final product release if different from the manufacturer.** *(Add as many rows as necessary)*
Name: Company name: Address: Country: Telephone: Telefax: E-Mail: **If the manufacturer is different to 1.1 above, explain the relationship:**	
1.2.13.2	**Name(s) and complete address(es) of the manufacturer(s) of the active pharmaceutical ingredient(s) (API)** *(Add as many rows as necessary)*
	Name: Company name: Address: Country: Telephone: Telefax: **E-Mail:**
1.2.14 Manufacturing and marketing authorisation(s)/international registration status	

1.2.14.1 Product Marketing Authorisation issued by the national regulatory authority in the country of origin and other countries (If not registered in the country of origin state reasons).

Authorised Country:	Withdrawn (by applicant after authorisation) Country:
Date of authorisation (dd-mm-yyyy):	Date of withdrawal (dd-mm-yyyy):
Proprietary name:	Proprietary name:
Authorisation number:	Reason for withdrawal:
Refused	Suspended/revoked (by competent authority)
Country:	Country:
Date of refusal (dd-mm-yyyy):	date of suspension/revocation (dd-mm-yyyy):
Reason for Refusal:	Reason for suspension/revocation:
	Proprietary name:

1.2.14.2 Attach a valid certificate of pharmaceutical product from the country of origin.

1.2.14.3 Valid Manufacturing authorisation from the country of origin and Good Manufacturing Practice certificate (GMP).

1.2.14.4 Valid manufacturing contract agreement between the applicant and manufacturer, in addition, for loan license manufacturing a valid manufacturing contract agreement and Supporting documentation from the competent drug regulatory authority for the manufacturing license code should be submitted.

1.2.15 Copy of Certificate of Suitability of the European Pharmacopoeia (CEP) including any annexes. (if applicable)

1.2.16 Name and complete address of the Authorised Local Representative of the applicant (local agent)

Name:
Company name:
Address:
Country:
Telephone:
Fax:
e-mail:

1.3 Prescribing information

1.3.1 Product information for health professionals (Products subject to medical prescription)
1.3.2 Patient Information leaflet
1.3.3 Labelling (Outer and inner labels)

1.4 Samples of the product as per OFFICIAL sample schedule

1.5 Batch number(s) of the FPPs used in
Clinical/bioequivalence studies
Stability studies

Validation/production scale batches Comments [e.g., batch size, explanation of NA (not applicable) answers]

Composition of clinical, primary stability and validation/production FPP batches (kg)

Ingredients	Administration Unit		Bioequivalence <batch number>		Primary stability <batch number>		Production <batch number>	
	Mg	%*	Kg	%*	Kg	%*	kg	%*
Core tablet / capsule contents / injections / suspensions, etc. (*Please delete / change which does not apply*)								
API 1								
API 2								
API 3								
as necessary								
Excipient 1								
Excipient 2								
Excipient 3								
Please add / delete as many rows as necessary								
Subtotal 1								
Purified water/other solvent(s)								
Film coat / capsule shell / printing ink (*Please delete / change which does not apply*)								
Proprietary film-coating mixture**								
Please add / delete as many rows as necessary								
Subtotal 2								
Grand total								
Purified water/other solvent(s)								
Equivalence of the composition or justified differences			The compositions of the bioequivalence, stability and validation batches are the same and differences are justified. (*Please delete / change which does not apply*)					
* Each ingredient is expressed as a percentage of the grand total.								

** All components (……..) of the proprietary mixture are described in the compendia		
MODULE 2: CHEMICAL, PHARMACEUTICAL, NON-CLINICAL AND CLINICAL OVERVIEWS AND SUMMARIES		
2.1	**CTD TABLE OF CONTENTS OF MODULES 2, 3, 4, AND 5**	
2.2	**INTRODUCTION**	
2.3	**QUALITY OVERALL SUMMARY**	
2.3.S	**OVERVIEW OF ACTIVE PHARMACEUTICAL INGREDIENT(S) [API(S)]**	
2.3.S.1	General Information of the API(S)	
2.3.S.1.1	Nomenclature	
2.3.S.1.2	Structure	
2.3.S.1.3	General Properties of the API(s)	
2.3.S.2	Manufacture of the API(S)	
2.3.S.2.1	Name and address of API(s) Manufacturer	
2.3.S.2.2	Description of Manufacturing Process and Process Controls	
2.3.S.2.3	Control of Materials used in Manufacture of API	
2.3.S.2.4	Controls of Critical Steps and Intermediates	
2.2.S.2.5	Process Validation and/or Evaluation	
2.3.S.3	Characterization of the API(S)	
2.3.S.4	Control of the API(S))	
2.3.S.5	Reference Standards or Materials of the API(S)	

2.3.S.6	Container Closure System of the API(S)	
2.3.S.7	Stability of the API(S)	
2.3.P	**OVERVIEW OF FINISHED PHARMACEUTICAL PRODUCT [FPP]**	
2.3.P.1	Description and Composition of the FPP	
2.3.P.2	Pharmaceutical Development of the FPP	
2.3.P.3	Manufacture of the FPP	
2.3.P.4	Control of Excipients for the FPP	
2.3.P.5	Control of the FPP	
2.3.P.6	Reference Standards or Materials of the FPP	
2.3.P.7	Container Closure System of the FPP	
2.3.P.8	Stability of the FPP	
2.3. A	**APPENDICES**	
2.3.A.1	Facilities and Equipment	
2.3.A.2	Adventitious Agents Safety Evaluation	
2.3.A.3	Excipients	
	REGIONAL INFORMATION	
2.4	**SUMMARY OF NON-CLINICAL DOCUMENTATION AND CLINICAL DOCUMENTATION**	
2.4.1	**FOR NEW CHEMICAL ENTITIES**	
2.4.1.1	Non-clinical overview	
2.4.1.2	Non-clinical written and tabulated summaries	
2.4.1.3	Clinical overview	
2.4.1.3	Clinical summary	
2.5.1	**GENERIC DRUG APPLICATIONS**	

2.5.2	Clinical Overview and Summary	
2.5.3	Product Development Rationale	
2.5.4	Overview of Biopharmaceutics Studies	
2.5.5	Summary of Biopharmaceutics Studies and Associated Analytical Methods	
MODULE 3: CHEMICAL-PHARMACEUTICAL DOCUMENTATION		
3.1	**TABLE OF CONTENTS OF MODULE 3**	
3.2	**BODY OF DATA**	
3.2.1	**PARTICULARS OF ACTIVE PHARMACEUTICAL INGREDIENT(s) [API(s)]**	
3.2.1.1	General Information of the API(S)	
3.2.1.2	Manufacture of the API(S)	
3.2.1.3	Characterization of the API(S)	
3.2.1.4	Control of the API(S))	
3.2.1.5	Reference Standards or Materials of the API(S)	
3.2.1.6	Container Closure System of the API(S)	
3.2.1.7	Stability of the API(S)	
3.2.2	**PARTICULARS OF FINISHED PHARMACEUTICAL PRODUCT(S) [FPP(S)]**	
3.2.2.1	Description and Composition of the FPP(S)	
3.2.2.2	Pharmaceutical Development of the FPP(S)	
3.2.2.3	Manufacture of the FPP(S)	
3.2.2.4	Control of Excipients for the FPP(S)	
3.2.2.5	Control of the FPP(S)	
3.2.2.6	Reference Standards or Materials of the FPP(S)	
3.2.2.7	Container Closure System of the FPP(S)	

3.2.2.8	Stability of the FPP(S)	
3.2.3	**APPENDICES**	
3.2.3.1	Facilities and Equipment	
3.2.3.2	Adventitious Agents Safety Evaluation	
3.2.33	Novel Excipients	
MODULE 4: NON-CLINICAL STUDY REPORTS FOR NEW CHEMICAL ENTITIES ONLY		
4.1	**TABLE OF CONTENTS OF MODULE 4**	
4.2	**STUDY REPORTS**	
4.3	**LITERATURE REFERENCES**	
MODULE 5: CLINICAL STUDY REPORTS		
5.1	**NEW CHEMICAL ENTITIES ONLY**	
5.1.1	Table of Contents of Module 5	
5.1.2	Tabular Listing of All Clinical Studies	
5.1.3	Clinical Study Reports	
5.1.4	Literature References	
5.2	**INTERCHANGEABILITY OF GENERIC DRUGS – (GENERIC DRUG APPLICATIONS ONLY)**	
5.2.1	**REPORTS OF BIOPHARMACEUTIC STUDY(IES)**	
5.2.1.1	Bioavailability (BA) study report	
5.2.1.2	*In Vitro* Dissolution Tests	
5.2.2.1.1	In vitro dissolution tests complementary to bioequivalence studies	
5.2.2.1.2	In vitro dissolution tests in support of biowaiver	

5.2.3	Other Clinical study data done to support efficacy and safety of the product	
5.3	**SAFETY AND RESIDUES DOCUMENTATION (FOR VETERINARY PRODUCTS ONLY)**	
5.3.1	Requirements for Animal Safety	
5.3.1.1	Laboratory Animal Studies	
5.3.1.2	Target Animal Safety Studies	
5.3.2	Requirements for Human Safety	
5.3.2.1	Laboratory Animal Toxicity Studies	
5.3.2.2	Microbiological Safety Studies (for antimicrobial products)	
5.3.2.3	Veterinary Antimicrobial Products	
5.3.2.4	Residue (Chemistry) Studies/data for food producing species only	

DECLARATION BY AN APPLICANT

1. I, the undersigned certify that all the information in this application form and accompanying documentation is correct, complete and true to the best of my knowledge.
2. I further confirm that the information referred to in my application dossier is available for verification during current GMP inspection.
3. The product shall not be imported, distributed for sale or advertised into the country until the product has been duly registered.
4. I also agree that the applicant will implement a Pharmacovigilance plan for this product in accordance with Official requirements
5. I also agree that I am obliged to follow the requirements of the relevant guidelines, which are related to pharmaceutical products.
6. I also consent to the processing of information provided.

Name:

……..…….

Position in the company:……

Signature: ……..……

Date:……..

- Do not make changes to the form in the process of applying. These changes may include but not limited to font, company art work including logos.
- Please fill in all relevant sections
- State if an item is attached and give identification/appendix or directions to locate item

Section 2 Application Form for Variation of a Registered Medicine and Health Product

APPLICATION FORM FOR VARIATION OF A REGISTERED HUMAN MEDICAL PRODUCT

1. Proprietary name	
1.1. Name of the active ingredient(s) (International Non-proprietary Name in English)	
1.2 Pharmacotherapeutic classification (Anatomic-Therapeutic Classification system)	
2. Pharmaceutical Dosage form:	
3. Type of change(s) (*State which type of Variation):*	
3.1 Other Application(s) *(Please provide brief information on any ongoing variation or other variation(s) submitted in parallel, or renewal application(s), or line-extension(s)*	
3.2 Scope *(Please specify scope of the change(s) in a concise way)*	
3.3 Background for change & Justification for Consequential change(s) (if applicable). *Please give brief background explanation for the proposed change(s) to your marketing authorization as well as a justification in case of consequential change(s)*	
3.5 Present *(Please specify precise present wording or specification)*	Proposed *(Please specify precise proposed wording or specification)*

In the case of changes to the Summary of Product Characteristics and/or package leaflet, applicants should always enclose a working model clearly showing the differences (new text and deleted text) between the proposed new version and the current text, previous version or reference text.

4. Details of applicant (Must be the holder of the marketing authorization/registration certificate) Name: Business Address: Postal Address: Country: Phone: Fax: Email:

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

A Regulation for Registration 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 Regulations for Registration 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