GOVERNMENT OF ZAMBIA

STATUTORY INSTRUMENT NO. 79 OF 2019

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances (Marketing Authorisation of Medicines) Regulations, 2019

ARRANGEMENT OF REGULATIONS

Copies of this Statutory Instrument can be obtained from the Government Printer, P.O. Box 30136, 10101 Lusaka. Price K64.00 each.

IN EXERCISE of the powers contained in sections 39 and 69 of the Medicines and Allied Substances Act, 2013, the following Regulations are made:

PART I
PRELIMINARY PROVISIONS

Title

1. These Regulations may be cited as the Medicines and Allied Substances (Marketing Authorisation of Medicines) Regulations, 2019.

Interpretation

2. In these Regulations, unless the context otherwise requires—

" active pharmaceutical ingredient " means a substance intended to exert 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, and may be used as is or in the manufacture of a pharmaceutical dosage form;

" batch " means a defined quantity of a starting material, packaging or medicinal product processed in a single process or series of processes and expected to be homogeneous;

" bio-availability " means the rate and extent of availability of an active pharmaceutical ingredient from a dosage form as determined by its concentration time curve in the systemic circulation or by its excretion in urine;

" bio-equivalence data " means the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical alternatives becomes available at the site of drug action administered;

" commercial pack " means the presentation of a finished medicinal product as it will be placed on market;

" composition " means a tabulation of ingredients represented in form of proportion, degree of strength, quality and purity in which the ingredients are contained in a medicinal product;

" container " means a bottle, jar, box, packet, sachet or other receptacle, not being a capsule or other article, in which the product is or is to be administered or consumed, and where the receptacle is or is to be contained in another receptacle, includes the former receptacle but not the latter receptacle;

" description of the product " means a full visual description of the medicinal product, including colour, size, shape and other relevant features;

" dosage form " means the form in which a medicinal product is presented, such as solution, suspension, elixir, eye drop, emulsion, ointment, suppository, tablet or capsule;

" excipient " means a substance intended to be used as is or in the manufacture of a medicinal product for a specific function, but does not exert pharmacological activity;

" expiry date " means the date given by the manufacturer and placed on the container of a medicinal product up to which the product is expected to remain within the given specifications if stored according to manufacturer's instructions;

" finished pharmaceutical product " means a product that has undergone all the stages of production, including packaging in its final container and labelling;

" formulation " means the composition of a dosage form, including the characteristics of its raw materials and the operations required to process it;

" general sale medicine (GS) " means a medicine which is intended to be supplied or sold without a prescription with or without the supervision of a registered pharmacist in a pharmacy or in any other licensed premises;

" general sale medicines veterinary (GSV) " means veterinary medicine which is intended to be supplied by any retailer approved by the Authority;

" herbal medicine " includes a herb, herbal material, herbal preparation and finished herbal product that contains as an active ingredient, a part of a plant or other plant material or combination;

" holder of marketing authorisation " means a person to whom a medicinal product has been issued a market authorisation and is responsible for all aspects of the medicinal product including quality, safety, efficacy and compliance with conditions of marketing authorisation;

" international non proprietary name " means a unique name of a medicine that is globally recognised and is public property;

" labelling " means affixing to or displaying on a container or package, the product information, ingredients and content of the product;

" local responsible person " means a person residing in Zambia and appointed in accordance with regulation 17;

" marketing authorisation number " means an identification number issued to a medicinal product granted marketing authorisation;

" pharmacy medicine (P) " means a medicine which is intended to be supplied or sold without a prescription but under the supervision of a registered pharmacist;

" pharmacy medicines veterinary (PV) " means veterinary medicine which is intended to be supplied by a registered veterinary surgeon, pharmacist or veterinary para professional with or without a prescription;

" prescription only medicine (POM) " means a medicine which is intended to be supplied, sold or dispensed only under a prescription issued by an authorised prescriber;

" prescription only medicine veterinary (POM V) " means veterinary medicines which is intended to be supplied on prescription by a veterinary surgeon;

" proprietary name " means the trade or brand name that is unique to a particular medicine and by which it is generally identified;

" quality standard " means the specifications used to control the nature, strength, purity, composition, quantity or other characteristics of an ingredient or finished pharmaceutical product to ensure that it is fit for its purpose;

" shelf life " means the period of time during which an active pharmaceutical ingredient or medicinal product, if stored correctly, is expected to comply with the approved specification as determined by stability studies on a number of batches of the active pharmaceutical ingredient or medicinal product;

" stability " means the ability of a medicine to retain its properties within approved specifications throughout its shelf life;

" WHO type certificate of a pharmaceutical product " means a certificate of the type defined in the World Health Organisation certification scheme on the quality of pharmaceutical products in international commerce; and

" veterinary medicine " means a substance or mixture of substances manufactured, sold or presented for use in-

(a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof, in an animal;

(b) restoring, correcting or beneficial modification of organic or mental functions in an animal; and

(c) an article intended for use as a component of any article specified in paragraphs *(a)* or *(b)*, but does not include a medical device or its component, part or accessory

Application for marketing authorisation
S.I. No. 38 of 2016

3. (1) A person who intends to place a medicine on the market shall apply to the Authority for a marketing authorisation in Form I set out in the Schedule on payment of the fee set out in the Medicines and Allied Substances (Fees) Regulations, 2016.

(2) The application referred to in sub-regulation (1) shall be accompanied by

(a) at least two samples of the product in the smallest proposed commercial pack size;

(b) a dossier which shall contain—

(i) a summary and overview of quality, non clinical and clinical data;

(ii) chemical, pharmaceutical and biological data relevant to the application;

(iii) non clinical data, where applicable; and

(iv) clinical or bio-equivalence data;

(c) in the case of a herbal medicine, documentation relating to the quality assessment, safety assessment and efficacy assessment of the herbal medicine; and

(d) any other information relating to the safety, quality and efficacy of the medicine in respect of which the application is made.

(3) The Authority shall, on receipt of an application for a marketing authorisation, conduct an assessment to evaluate the safety, quality and efficacy of the medicine in respect of which the application is made.

Request for additional information

4. The Authority may request an applicant to submit additional information or samples in relation to an application in Form II set out in the Schedule on payment of a prescribed fee.

Grant of marketing authorisation

5. The Authority shall grant a marketing authorisation in Form III set out in the Schedule, if the Authority is satisfied—

(a) with the information submitted on the safety, quality and efficacy of the medicine;

(b) with the labeling and packaging of the medicine;

(c) with the indications, dosage form, dosage and route of administration of the medicine; and

(d) that the medicine is manufactured in compliance with the requirements of current good manufacturing practices as recommended by the World Health Organisation or any other recognisedentity.

Rejection of application

6. (1) The Authority shall reject an applicationfor marketing authorisation if—

(a) the applicant fails to meet the requirements for the issue of the marketing authorisation;

(b) there is insufficient data to support the safety, quality and efficacy of the product;

(c) in the case of a local manufacturer, the pharmaceutical licence to manufacture is suspended or revoked;

(d) an ingredient contained in the medicine is banned or not recommended for any other reason as determined by the Authority;

(e) the medicine in respect of which the application is made is considered unregistrable based on treatment guidelines or disease patterns in the Republic; and

(f) the applicant provides false information in the application.

(2) The Authority shall, where it refuses a marketing authorisation under sub regulation (1), inform the applicant in Form IV set out in the Schedule.

Validity of marketing authorisation

7. A marketing authorisation is valid for five years, subject to the terms and conditions of the market authorisation.

Annual retention fee

8. (1) The holder of a marketing authorisation shall pay an annual retention fee to the Authority in respect of the following year at the end of every year during which the authorisation is valid, except the year when the authorisation is granted.

(2) The annual retention fee for the following year shall be—

(a) effective from 1st January of the year following the grant of the marketing authorisation; and

(b) paid to the Authority by 31st December of each year.

(3) Where a marketing authorisation is granted during the last quarter of a calendar year, the holder of the marketing authorisation shall be exempted from paying the annual retention fee for the following year.

(4) Where the holder of a marketing authorisation fails to pay the annual retention fee by 31st December for a particular product

(a) the marketing authorisation issued in respect of that product shall be suspended;

(b) the Authority shall not authorise the importation of the product;

(c) in case of locally manufactured products, the Authority shall not authorise the continued manufacture of the product; and

(d) the marketing authorisation in respect of the product may be revoked by the Authority.

Amendment of marketing authorisation

9. (1) A person who wishes to amend a marketing authorisation shall apply to the Authority in Form V set out in the Schedule on payment of a prescribed fee.

(2) The Authority shall, within ninety days from the date of receipt of an application for the amendment of a marketing authorisation, consider the application and notify the holder of the marketing authorisation of its decision.

Surrender of marketing authorisation

10. Where the holder of a marketing authorisation decides not to continue with the business to which the marketing authorisation relates, the holder shall notify the Authority and surrender the marketing authorisation.

Transfer of marketing authorisation

11. (1) A marketing authorisation is solely for use by the holder of the marketing authorisation and is not transferable to any other person without the prior approval of the Authority.

(2) A person who wishes to transfer a marketing authorisation shall apply to the Authority in Form VI set out in the Schedule on payment of a prescribed fee.

(3) The Authority shall, within sixty days from the date of receipt of the application for the transfer of the marketing authorisation, notify the applicant of the decision of the Authority in respect of the application.

(4) Where the Authority approves the transfer of a marketing authorisation, it shall issue a new marketing authorisation to the transferee.

Suspension of marketing authorisation

12. (1) The Authority may suspend a marketing authorisation if—

(a) there are concerns regarding the safety, quality or efficacy of the medicine to which it relates;

(b) the holder of the marketing authorisation fails to pay the annual retention fee;

(c) the holder of the marketing authorisation fails to comply with any term or condition of the marketing authorisation; or

(d) the medicine in respect of which the marketing authorisation was issued poses a risk or threat to public health.

(2) The Authority shall, before suspending a marketing authorisation, give notice to the holder of a marketing authorisation of the intention to suspend the marketing authorisation in Form VII set out in the Schedule.

(3) The Authority shall, if the holder of a marketing authorisation fails to remedy the defects within the period specified by the Authority in the notice issued in sub-regulation (2), suspend the marketing authorisation and notify the holder of the marketing authorisation in Form VIII set out in the Schedule.

(4) The holder of a marketing authorisation shall, during the period of suspension of a marketing authorisation, quarantine the affected medicine as directed by the Authority at the holder of the marketing authorisation's cost.

Restoration of marketing authorisation

13. (1) The Authority may restore a suspended marketing authorisation if the Authority is satisfied that corrective measures have been taken by the holder of the marketing authorisation as directed by the Authority.

(2) The Authority shall issue the notice of restoration of a suspended marketing authorisation in Form IX set out in the Schedule.

Revocation of marketing authorisation

14. (1) The Authority may revoke a marketing authorisation if the holder—

(a) contravenes the terms and conditions of the marketing authorisation;

(b) manufactures medicine that does not comply with the quality standard for that medicine;

(c) fails to comply with current good manufacturing practices;

(d) fails to comply with the terms and conditions for the suspension under regulation 12; or

(e) obtained the authorisation on the basis of fraud, negligence or misrepresentation.

(2) The Authority shall, before revoking a marketing authorisation, give notice to the holder of the marketing authorisation of the intention to revoke the marketing authorisation in Form X set out in the Schedule.

(3) The Authority shall, where the holder of a marketing authorisation fails to remedy the breaches specified in the notice within the period specified by the Authority, revoke the marketing authorisation and notify the holder in Form XI set out in the Schedule.

(4) The holder of a marketing authorisation shall, on the revocation of the marketing authorisation, recall and quarantine or dispose of the medicine to which the revocation relates as directed by the Authority at the holder of the marketing authorisation's cost.

Application for duplicate marketing authorisation

15. (1) A holder of a marketing authorisation whose marketing authorisation is lost, defaced or damaged may apply for a duplicate marketing authorisation in Form XII set out in the Schedule on payment of a prescribed fee.

(2) The Authority shall, within fourteen days of receipt of an application under subregulation (1), issue a duplicate marketing authorisation to the applicant.

Renewal of marketing authorisation

16. (1) A person who wishes to renew a marketing authorisation shall apply to the Authority at least one hundred and eighty days before the expiry date of the marketing authorisation in Form XIII set out in the Schedule on payment of a prescribed fee.

(2) An application for the renewal of a marketing authorisation shall be accompanied by—

(a) a consolidated report of any amendments made to the marketing authorisation, including adverse drug reaction reports and safety updates; and

(b) the product quality review report.

(3) The Authority shall renew a marketing authorisation if the holder has complied with the terms and conditions of the marketing authorisation.

(4) The Authority shall, where the Authority refuses to renew a marketing authorisation, notify the applicant in Form IV set out in the Schedule.

(5) A holder of a marketing authorisation whose application for renewal has been rejected may submit an application for a marketing authorisation in accordance with regulation 3.

Local responsible person Act No. 10 of 2017

17. (1) Subject to the Companies Act, 2017 and any other relevant written law, a foreign based applicant shall appoint a local responsible person to—

(a) submit an application, document and sample of products to the Authority on behalf of the applicant or holder of the marketing authorisation; and

(b) receive the decision of the Authority relating to the application on behalf of the applicant or holder of the marketing authorisation.

(2) Subject to sub regulation (1), where the application is granted, the holder of the marketing authorisation shall ensure that a local responsible person implements the pharmacovigilance plan on behalf of the foreign holder of the marketing authorisation.

Categories of distribution of medicines

18. (1) The Authority shall, where it grants a marketing authorisation, specify the appropriate category of distribution of the medicine which relates to the marketing authorisation.

(2) A person may sell or supply medicine for human use under the following categories:

(a) prescription only medicine;

(b) pharmacy medicine; and

(c) general sale medicine.

(3) A person may sell or supply veterinary medicine under the following categories:

(a) prescription only medicine - veterinary;

(b) pharmacy medicine veterinary; and

(c) general sale medicine veterinary.

Re-categorisation of medicine

19. The Authority shall take into consideration the safety profile of the medicine when determining the category of distribution and may move certain medicines from one category to another.

Labelling and packaging requirements for medicine

20. (1) A holder of a marketing authorisation shall label the primary package or container of a medicine to show—

(a) the name and dosage form of the medicine;

(b) the name and quantity of active pharmaceutical ingredient or in case of a herbal medicine, a botanical, english or other name, and the quantity of each ingredient;

(c) the quantity or volume of the medicine per unit pack;

(d) the indications and directions for use, including the target species in case of veterinary medicine;

(e) the storage instructions;

(f) the expiry date;

(g) the batch number;

(h) the marketing authorisation number;

(i) the name and address of the holder of the marketing authorisation;

(j) suitable coding;

(k) the name of the manufacturer, if different from the holder of the marketing authorisation;

(l) the category of distribution;

(m) a precautionary statement "Keep away from the reach of children";

(n) in case of a veterinary medicine, a statement "For Veterinary Use Only"; and

(o) any other information required by the Authority for purposes of the Act.

(2) Where the space on a primary container of medicine is not adequate to accommodate the information specified in sub-regulation (1), the holder of a marketing authorisation shall label the primary container to indicate the—

(a) name and dosage form of the medicine;

(b) quantity or volume of the medicine per unit pack;

(c) expiry date;

(d) name and quantity of active ingredient, or in case of a herbal medicine, a botanical, English or other name, and the quantity of each ingredient;

(e) marketing authorisation number;

(f) storage instructions; and

(g) batch number, except that all the particulars specified under sub regulation (1) shall be set out on the secondary package.

(3) A holder of a marketing authorisation shall, where the container of medicine is unable to accommodate the information under sub-regulation (2), indicate the details of labelling requirements for each type of container

as may be determined by the Authority.

(4) This regulation does not apply to medicine that is re-packaged for dispensing.

(5) Despite the other provisions of this regulation, the Authority may waive the labeling requirements, as appropriate, to ensure the safety, quality and efficacy of the medicine.

Package insert for medicine

21. An original container of a medicine shall be accompanied by a package insert printed in legible letters in English stating the

(a) name and dosage form of the medicine;

(b) name and quantity of active pharmaceutical ingredient, or in case of a herbal medicine, a botanical, English or other name, and the quantity of each ingredient;

(c) indications, in case of a veterinary medicine, specifying target species;

(d) dosage and directions for use, in case of a veterinary medicine, specific to each target species;

(e) contra-indications;

(f) side effects;

(g) drug interactions;

(h) precautions and warnings, including withdrawal periods, in case of a veterinary medicine used in food producing animals;

(i) symptoms, signs, treatment and management of overdose;

(j) presentation of the medicine;

(k) description of packaging and container closure system;

(l) storage instructions;

(m) shelf life;

(n) name and address of the holder of the marketing authorisation; and

(o) name of the manufacturer, if different from the holder of the marketing authorisation.

Patient information leaflet

22. A holder of a marketing authorisation shall provide a patient information leaflet for general sale medicine and medicine used in chronic conditions.

Revocation of S.I. No. 47 of 1993

23. The Pharmacy and Poisons (Medicines) (Importation, Manufacture and Sale) Order, 1993, is revoked.

SCHEDULE

(*Regulations* 3, 4, 5, 6, 9, 11, 12, 13, 14, 15, 16 *and* 18)

PRESCRIBED FORMS

FORM I

(*Regulations* 3 (1) *and* 14(5))

(*To be completed in triplicate)*

The Medicines and Allied Substances Act, 2013

(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

APPLICATION FOR A MARKETING AUTHORISATION				
Please complete in block letters	Shaded fields for official use only	Application No.		
		Date and Time		
Information Required		*Information Provided*		√
PART I **PARTICULARS OF APPLICANT**				
A.	**PARTICULARS OF COMPANY**			
1.	*(a)* Name of business entity			
	(b) Tax Payer Identification Number (where applicable)			
2.	Type of business entity			
3.	Business premises			
	(a) Plot No:			
	(b) Street:			
	(c) Telephone No:			
	(d) Fax No:			
	(e) Mobile No:			
	(f) Email address			
	(g) Postal address			
	(h) Town			
	(i) District			
	(j) Province			
	(k) Country			
B	**CONTACT PERSON**			
	(a) Name			
	(b) Designation			
	(c) Physical address			
	(d) Postal address			
	(e) Phone			
	(f) fax			
	(g) Email address			
C	**LOCAL RESPONSIBLE PERSON (Applicable to foreign based applicants)**			
	(a) Name			
	(b) Designation			
	(c) Physical address			
	(d) Postal address			

	(e) Phone		
	(f) fax		
	(g) Email address		
	PART II **PARTICULARS OF THE PRODUCT**		
1.	Name of the medicine:		
2.	International non-proprietary names of the active pharmaceutical ingredient, including form (salt, hydrate, polymorph) and strength (in case of a herbal medicine, specify the botanical, English or any other name and the quantities of each ingredient)		
3.	ATC code		
4.	Dosage form		
5.	Route of administration		
6.	Name and site address of source of the active raw material (in case of herbal medicine)		
7.	Container, closure and administration system		
8.	Proposed indication (specify target species in case of veterinary medicine)		
9.	Package size		
10.	Shelf life (months)		
11.	Storage conditions/instructions		
12.	Proposed category of distribution		
13.	Marketing authorisation status in other countries		
	PART III **PARTICULARS OF MANUFACTURER**		
	Name, address and responsibility (e.g. fabrication, packaging, labelling, testing etc.) of each manufacturer, including contractors and each proposed production site or facility involved in manufacturing and testing of the product:		
1.	Name:		
2.	Physical address (include block(s)/unit(s) if applicable		
3	Responsibility:		
	If more than one site is involved (e.g. manufacturing of dosage form, primary packaging, release etc.), clearly identify the site for each stage.		
	include copies of the latest GMP certificate for manufacturer and packers or a copy of the appropriate manufacturing licence		

PART IV
COMPOSITION

List of all components of the finished pharmaceutical product and their amounts on a per unit, batch and percentage basis including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any

Ingredients and quality standard (in case of a herbal medicine, specify the botanical, english or any other name	**Function (reason for inclusion)**	**Strength (label claim)**			
		Quantity per unit dosage form (e.g. mg/tablet)	**% per unit dosage form**	**Quantity per batch**	**% per batch**
<complete with appropriate title e.g. core tablet, contents of capsule, powder for injection>					
Subtotal 1					
<complete with appropriate title e.g. film-coating>					
Subtotal 2					
Total					

8. **PART V: TYPE OF APPLICATION**

Indicate the type of medicine, the type of data included as proof of efficacy, and the review procedure using a check mark (√) or a cross (X)

Human Medicine		NCE		Data as proof of efficacy:	
Chemical		Multisource		Pre-clinical	
Biological		Biosimilar		Clinical	
Veterinary Medicine:				Biostudy	
Chemical				BCS biowaiver	
Biological				Bibliography	
Herbal:					
Review Procedure					
Routine		Abridged		Fast Track (Expedited)	

DECLARATION AND SIGNATURE:

I declare that all the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I understand that submission of false information shall render the application void and that if approval is granted, the market authorisation may be revoked.

Particulars of the Person signing on behalf of the Applicant

…… ……..

Name *Designation*

…….. ……

Signature *Date*

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Date of Submission: ……..….

Application Number: ……..……..

Payments Receipt Number: ……..……..…

Application complete (Proceed for evaluation): ……..……..…..

Application incomplete (refer to applicant for additional information):

……

OFFICIAL STAMP

FORM II
(*Regulations* 4 (1))

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

REQUEST FOR ADDITIONAL INFORMATION

Application No:……

To: ……

Address: ……

You are requested to furnish, within…….. days of this Notice, the following information or documents in respect of your application for …….

(a) ……..

(b) ……..

(c) ……

(d) ……..

If you fail to furnish the requested information within the stipulated period, your application will be treated as invalid and shall be rejected.

Dated this…… day of ……., 20…….

……
Director-General

OFFICIAL STAMP

FORM III
(*Regulations* 5 (1))

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

MARKETING AUTHORISATION

Marketing Authorisation No. MA ……/……

Name of Medicine:……

Dosage form:……

Pack size	Shelf life (Months)	Category of distribution
……..….	…….	……...…..
……...….	……	……..……
……..….	……	…….....
Name of active ingredient	Quality standards	Strength
……	……...	……..
……	……	……..
……..……..	……...…..	……..

Name and address of holder of marketing authorisation:
…….....……
…….....
….……
Valid until …….…….

The terms and conditions of the marketing authorisation are attached herewith.

…….…… ……...……
Director-General *Date of issue*

SEAL

TERMS AND CONDITIONS OF THE MARKETING AUTHORISATION

The holder of a marketing authorisation shall—

(a) ensure that the medicine—

(i) is manufactured in compliance with the current Good Manufacturing Practices (cGMP) as recommended by the World Health Organisation (WHO) or any other recognised entity;

(ii) conforms with the quality standards, safety and efficacy and is suitable for the purpose for which it is intended;

(iii) conforms to the summary of product characteristics;

(b) ensure compliance with good distribution practices and that the medicine is supplied in accordance with the requirements applicable to the categories of distribution specified on this marketing authorisation and with regulations on labeling of medicine;

(c) maintain an appropriate pharmacovigilance system for monitoring, detecting and reporting adverse drug reactions and the performance of products granted marketing authorisation;

(d) pay to the Authority the annual retention fees, sample analysis fees and other fees as prescribed;

(e) ensure that the marketing authorisation is not transferred without the written approval of the Authority;

(f) for a foreign-based holder of marketing authorisation, appoint a local responsible person;

(g) notify the Authority of any change that requires an amendment to a marketing authorisation;

(h) when necessary or as directed by the Authority, withdraw any product from the market that is injurious to, or is likely to be injurious to public health; and

(i) provide additional information or product sample when required to do so by the Authority for purposes of the Act.

NOTE:

Non-compliance with any of the terms or conditions of a marketing authorisation will result in suspension or revocation of the marketing authorisation.

FORM IV
(*Regulations* 6 (2) and 16 (4)

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

NOTICE OF REJECTION OF APPLICATION FOR A MARKETING AUTHORISATION/ RENEWAL OF MARKETING AUTHORISATION

Application No.:……

(1) Here insert the full names and address of the applicant

To (1)…….....…….....
……

(2) Here insert the reference No. of the application and the product name

(3) Here insert the applicable application

IN THE MATTER OF (2) ……..... you are notified that your application for (3) a marketing authorisation/renewal of a marketing authorisation has been rejected by the Authority on the following grounds:

(a)…….....……..…….....……

(b)…….....……..……

(c)…….....…….....……

(d)…….....……

.

Dated this ……day of ……..…… 20……...

.....

Director-General

OFFICIAL STAMP

FORM V
(*Regulation* 9(1))
(*To be completed in triplicate*)

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

APPLICATION FOR AMENDMENT OF MARKETING AUTHORISATION				
Please complete in block letters		Shaded fields for official use only	Application No.	
			Date and Time	
Information Required		*Information Provided*		√
PART 1 **PARTICULARS OF APPLICANT**				
A	**BUSINESS APPLICANT**			
1.	*(a)*Name of applicant			
	(b) Tax Payer Identification Number (where applicable)			
2.	Type of entity			
3.	Business premises			
	(a) Plot No:			
	(b) Street:			
	(c) Postal address			
	(d) Telephone No:			
	(e) Fax No:			
	(f) Mobile No:			
	(g) Email address			
	(h) Town			
	(i) District			
	(j) Province			
	(k) Country			
B	**CONTACT PERSON**			
	(a) Name			
	(b) Physical address			
	(c) Postal address			
	(d) Phone			
	(e) fax			
	(f) Email address			
C	**LOCAL RESPONSIBLE PERSON**			
	(a) Name			
	(b) Designation			
	(c) Phone			
	(d) Fax			
	(e) Email address			

	PART II **PARTICULARS OF PRODUCT**		
	(a) name of the product		
	(b) marketing authorization No.		
	(c) strength(s)		
	(d) pack size(s)		
	(a) dosage form		
	PART III **TYPE OF AMENDMENT**		
4.	**PARTICULARS OF AMENDMENT**	**DESCRIPTION OF AMENDMENT(S)**	
	1.		
	2.		
	3.		
5.	**EXISTING**	**PROPOSED AMENDMENT**	**REASONS FOR AMENDMENT**
6.	**Attachment**		
	Relevant documents relating to proposed amendment as required by the Authority		

DECLARATION AND SIGNATURE

I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief.

Particulars of the Person signing on behalf of the Applicant

…… ……..

Name *Designation*

…….. ……

Signature *Date*

FOR OFFICIAL USE ONLY

Date of Submission: ……..……..
Application Number: ……..…….

Payments Receipt Number: ……..……..…..

Application accepted (Proceed for inspection): ……..……..…..

Application rejected (Notify applicant) ……..……..

……..……

OFFICIAL STAMP

FORM VI
(*Regulation* 11(2))
(*To be completed in triplicate*)

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

APPLICATION FOR TRANSFER OF MARKETING AUTHORISATION					
Please complete in block letters		Shaded fields for official use only	Application No.		
			Date and Time		
Information Required		*Information Provided*			√
PART I **PARTICULARS OF APPLICANT**					
A	**DETAILS OF CURRENT HOLDER OF MARKETING AUTHORISATION**				
1.	*(a)* Name of applicant				
	(b) TPIN				
2.	Type of entity				
3.	Business premises				
	(a) Plot No:				
	(b) Street:				
	(c) Telephone No:				
	(d) Fax No:				
	(e) Mobile No:				
	(f) Email address				
	(g) Postal address				
	(h) Town				
	(i) District				
	(j) Province				
	(k) Country				
B	**CONTACT PERSON**				
	(a) Name				
	(b) Physical address				
	(c) Postal address				
	(d) Phone				
	(e) fax				
	(f) Email address				
C	**LOCAL RESPONSIBLE PERSON**				
	(a) Name				
	(b) Designation				
	(c) Phone				
	(d) Fax				
	(e) Email address				

	PART II **PARTICULARS OF TRANSFEREE**		
1.	*(a)* Name of applicant		
	(b) TPIN		
2.	Type of entity		
3.	Business premises		
	(a) Plot No:		
	(b) Street:		
	(c) Postal address		
	(d) Telephone No:		
	(e) Fax No:		
	(f) Mobile No:		
	(g) Email address		
	(h) Town		
	(i) District		
	(j) Province		
B	**INDIVIDUAL TRANSFEREE**		
	(a) Name		
	(b) Physical address		
	(c) Postal address		
	(d) Phone		
	(e) fax		
	(f) Email address		
C	**LOCAL RESPONSIBLE PERSON OF TRANSFEREE**		
	(a) Name		
	(b) Designation		
	(c) Phone		
	(d) Fax		
	(e) Email address		
	PART III		
	PARTICULARS OF THE MEDICINE		
1.	Name of medicine		
2.	Marketing authorisation number		
3.	Strength		
4.	Pack size(s)		
5.	Dosage form		
6.	Proprietary name		
4.	**ATTACHMENTS**		
	Contract of sale or acquisition of business between the holder of market authorisation and the proposed transferee		
	Copy of original market authorisation		

DECLARATION AND SIGNATURE

I declare that all the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I understand that submission of false information shall render the application void and that if the market authorisation is granted, it shall be revoked.

Particulars of the Person signing on behalf of the Applicant

…… ……

Name *Designation*

…… ……

Signature *Date*

FOR OFFICIAL USE ONLY

Date of Submission: ……..……..

Application Number: ……..……..

Payments Receipt Number: ……..……..

Application accepted (Proceed for inspection): ……..……..

Application rejected (Notify applicant): ……..……..

……

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FORM VII
(*Regulation* 12(2))

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

NOTICE OF INTENTION TO SUSPEND A MARKETING AUTHORISATION

(1) Here insert name of holder of marketing authorisation

To (1)…….....…….....

……

(2) Here insert of medicine and marketing authorisation number

IN THE MATTER OF (2).....you are hereby notified that the Authority intends to suspend your marketing authorisation on the following grounds:

(a)…….....……..…….....……

(b)…….....……..……

(c)…….....…….....……

(d)…….....……

(3) Here insert number of days

Accordingly, you are requested to show cause why your marketing authorisation should not be suspended and to take action to remedy the breaches set out in paragraphs ..... (above) within (3).....days of receiving this notice. Failure to remedy the said breaches shall result in the suspension of your marketing authorisation.

Dated this ……day of …….....…… 20……...

.....

Director-General

OFFICIAL STAMP

FORM VIII
(*Regulation* 12(3))

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

NOTICE OF SUSPENSION OF MARKETING AUTHORISATION

(1) Here insert name of holder of marketing authorisation

To (1)……..……..……..
……

(2) Here insert name of medicine and marketing authorisation number

IN THE MATTER OF (2) ..... you are hereby notified that your marketing authorisation has been suspended for (3) ……..…….. on the following grounds:

(a)…….....……..……..……

(b)…….....……..……

(c)…….....……..……

(3) Here insert period of suspension

Accordingly, you are requested to take action to remedy the breaches set out in paragraphs ..... (above) within

(3) Here insert period of days

(4) ..... days of receiving this Notice. Failure to remedy the said breaches shall result in the revocation of your marketing authorisation.

Dated this ……day of ……..……..…… 20……...

.....
Director-General

OFFICIAL STAMP

FORM IX
(*Regulation* 13(2))

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

NOTICE OF RESTORATION OF MARKETING AUTHORISATION

(1) Here insert name of holder of marketing authorisation

To (1)…….....…….....
……

(2) Here insert name of medicine and marketing authorisation number

IN THE MATTER OF (2).....you are hereby notified that your marketing authorisation has been restored.

Note that you are required to comply with the terms and conditions attached to the marketing authorisation.

Dated this …….day of …….....…… 20……...

.....
Director-General

OFFICIAL STAMP

FORM X
(*Regulation* 14(2))

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

NOTICE OF INTENTION TO REVOKE MARKETING AUTHORISATION

(1) Here insert name of holder of marketing authorisation

To (1)……..……..……..……

(2) Here insert name of medicine and marketing authorisation number

IIN THE MATTER OF (2).....you are hereby notified that the Authority intends to revoke your marketing authorisation on the following grounds:

(a)…….....……..……

(b)…….....……..……

(c)…….....……..……

(d)…….....……..……

Accordingly, you are requested to show cause why your marketing authorisation should not be revoked for the breaches set out in paragraphs ..... (above) within

(3) Here insert number of days

(3) ..... days of receiving this notice. Failure to remedy the said breaches shall result in the revocation of your marketing authorisation.

Dated this ……day of ……..……..…… 20……..

.....
Director-General

OFFICIAL STAMP

FORM XI
(*Regulation* 14(3))

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

NOTICE OF REVOCATION OF MARKETING AUTHORISATION

(1) Here insert name of holder of marketing authorisation

To (1)……..……..……..……

(2) Here insert name of medicine and marketing authorisation number

IN THE MATTER OF (2)..... you are hereby notified that your marketing authorisation has been revoked on the following grounds:

(a)…….....……..……

(b)…….....……..……

(c)…….....……..……

(d)…….....……..……

You are therefore required to surrender the marketing authorisation to the Authority within twenty one days from the date of revocation.

You are also required to comply with the terms and conditions attached.

Dated this ……day of ……..……..…… 20……...

.....

Director-General

OFFICIAL STAMP

FORM XII
(*Regulation* 15(1))
(*To be completed in triplicate*)

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

APPLICATION FOR A DUPLICATE MARKETING AUTHORISATION

Please complete in block letters	Shaded fields for official use only	Application No.	
		Date and Time	

	Information Required	*Information Provided*	√
1.	Name of business entity/individual/local responsible person		
2.	Marketing Authorisation No.		
3.	Physical Address		
4.	Affidavit of loss or damage to marketing of authorisation		

DECLARATION AND SIGNATURE
I declare that all the information I have stated is correct and truthful to the best of my knowledge and belief.

Particulars of the Person signing on behalf of the Applicant

…… ……..
Name *Designation*

…….. ……
Signature *Date*

FOR OFFICIAL USE ONLY

Date of Submission: ……..

Application Number: ……...
Payments Receipt Number: ……
Application Accepted : ……..
Application Rejected (Notify applicant): ……..…
……...

OFFICIAL STAMP

FORM XIII
(*Regulation* 16(1))
(*To be completed in triplicate*)

The Medicines and Allied Substances Act, 2013
(Act No. 3 of 2013)

The Medicines and Allied Substances
(Marketing Authorisation of Medicines) Regulations, 2019

APPLICATION FOR RENEWAL OF MARKETING AUTHORISATION					
Please complete in block letters		Shaded fields for official use only	Application No.		
			Date and Time		
Information Required		*Information Provided*			√
A	**PRODUCT DETAILS**				
1.	Name of Product				
	Marketing Authorisation Number				
2.	Name of holder of market authorisation				
	(a) Tax Payer Identification Number (where applicable)				
	(b) Plot No:				
	(c) Street:				
	(d) Telephone No:				
	(e) Fax No:				
	(f) Mobile No:				
	(g) Email address				
	(h) Postal address				
	(i) Town				
	(j) District				
	(k) Province				
	(l) Country				
B	**CONTACT PERSON**				
	(a) Name				
	(b) Physical address				
	(c) Postal address				
	(d) Phone				
	(e) fax				
	(f) Email address				
C	**LOCAL RESPONSIBLE PERSON**				
	(a) Name				
	(b) Designation				
	(c) Phone				
	(d) Fax				
	(e) Email address				
3.	**Attachment**				
	Relevant documentation and additional data as outlined in the guidelines on Renewal of Marketing Authorisation				

Name of Applicant (individual or authorised representative)

Date: …… *Signature:* ……

FOR OFFICIAL USE ONLY

Received by: …… Receipt No: ……..
Amount Received: ……. …
Serial No. of application: ……..... …….

OFFICIAL STAMP

DR C. CHILUFYA,
Minister of Health

LUSAKA
18th November, 2019
[MH/101/16/1]