



Document No.: MA/GUD/010
**Guidelines on Advertising, Marketing and
Promotion of Medicines and Allied
Substances**

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Zambia Medicines Regulatory Authority

GUIDELINES ON ADVERTISEMENT, MARKETING AND PROMOTION OF MEDICINES AND ALLIED SUBSTANCES

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Version 1.0





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i. Abbreviations

MAH	Marketing Authorisation Holder
LPR	Live Presenter Mention
LRP	Local Responsible Person
ZAMRA	Zambia Medicines Regulatory Authority



ii. **Definitions**

The definitions below apply specifically to the terms used in this guideline:

Act	means the Medicines and Allied Substances Act (No.3) of 2013;
Advertisement	means any representation by any means whatsoever for the purpose of promoting, directly or indirectly, the sale or disposal of any medicine or allied substance;
Allied substances	include acaricides, cosmetics, disinfectants, food supplements, feed additives and supplements, medical and surgical sundries, medical devices and condoms;
Applicant	means marketing authorisation holder or appointed local responsible person;
Authority	means the Zambia Medicines Regulatory Authority (ZAMRA) established under section four of the Medicines & Allied Substances Act (No. 3) of 2013;
Health Practitioner	has the meaning assigned to the words in the Health Professions Act, 2024 and includes a nurse or midwife registered under the Nurses and Midwives Act, 2019 and Veterinary Para-professional and Veterinary surgeon registered under the Veterinary and Veterinary Para-professional Act (No. 45), 2010.
Health Professional	includes members of the medical, dental, pharmacy and nursing profession, Veterinary surgeons, and any other person who in the course of their professional activities may prescribe, supply or administer a medicine or allied substance;
Label	means any tag, brand, and mark, pictorial or other descriptive matter written, printed, brailled, marked, embossed or impressed on or attached to a container



of any product;

Live Presenter Mentions (LPMs) Advertisement means a ZAMRA-approved advertisement text presented by a person in a studio or any other functions;

Marketing means the process of promoting, branding, and commercializing medicines and allied substances to the target audience for purposes of increasing sales

Marketing Authorisation means the authorisation granted, under section thirty-nine of the Act, for the placement of a medicine or allied substance on the market;

Medical sales representative means an individual appointed by a MAH or LRP to market or promote a medicine or allied substance to the general public or health professionals.

Medicine means human medicine, veterinary medicine, medicinal product, herbal medicine or any substance or mixture of substances for human or veterinary use intended to be used or manufactured for use for its therapeutic efficacy or for its pharmacological purpose in the diagnosis, treatment, alleviation, modification or prevention of disease or abnormal physical or mental state or the symptoms of disease in a person or animal;

Persons qualified to Prescribe or supply medicines means a health practitioner authorised to prescribe or supply a particular medicine or allied substance;

Product means medicine or allied substance;

Product information means product information for healthcare professionals and the public as

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approved by the Authority;

Promotion is defined as the informal and persuasive activities by a marketing authorisation holder or distributor of medicines or allied substances, or a body appointed by them, which induces the prescription, supply, purchase and /or sale of the medicines or allied substances;

Promotional material means an item used for the purpose of promoting a product such as information leaflet, booklet, writing pad, pen, calendar, mug and other material which has a specific product claim and/or bearing a product name supplied separately from the product;

Public event means a formal meeting or conference by relevant experts where there is an exchange of scientific information relating to a medicine or allied substance, to recipients determined by the Authority; and

Sample means a representative of an authorised product with an imprint indicating that a product is a "Sample" and is "free" or "not for sale".

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1. Introduction

The Zambia Medicines Regulatory Authority is mandated to regulate the advertising, marketing and promotion of medicines and allied substances in the Republic of Zambia. These guidelines on advertising, marketing and promotion of medicines and allied substances are issued by the Zambia Medicines Regulatory Authority pursuant to section 68 of the Medicines and Allied Substances Act (No. 3) of 2013.

These guidelines constitute general principles relating to advertising, marketing and promotion of medicines and allied substances and are applicable to medicines and allied substances in all the categories of distribution.

All persons intending to advertise, market or promote medicines and allied substances are encouraged to use this guideline as appropriate to their spheres of competence, activity and responsibility and at the same time endeavour to develop their own sets of ethical standards in their own field relating to advertising, marketing and promotion of medicines.

All advertisements, marketing and promotions must comply with the Medicines & Allied Substances Act (No. 3) of 2013 and regulations made thereunder. The Authority may amend any part of this guideline from time to time.

2. Objective of the Guideline

The objective of this guideline is to provide guidance and establish standards for the advertising, marketing, and promotion of medicines and allied substances in Zambia. This guideline applies to all stakeholders involved in advertising, marketing and promotion of medicines and allied substances across various media platforms.

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3. Scope of the Guideline

This guideline is made for use by any person who intends to advertise, market or promote medicines and allied substances in Zambia. Advertising, marketing and promotional material that are subject to this guideline include, but not limited to:

- Aerial promotions such as on hot air balloons
- Cinema commercials
- Consumer leaflets
- Direct mail materials
- Internet materials including social media and press releases intended for internet publication
- Outdoor advertising, including exhibitions, billboards, advertisements on wall fences, canvas and motor vehicles
- Point of sale materials
- Posters
- Print and electronic advertisements
- Promotional materials including those used for direct selling activities such as booklets, pens, note pads, prescription pads, calendars, mugs, caps etc
- Adverts printed on motor vehicles or other vessels
- Sales promotions including direct sales in private and public places e.g in health facilities, pharmacies, salons, beauty parlours/spas, cosmetic stores, gyms, vehicles, door to door, etc
- Telephone help lines
- Television and radio commercials, talk shows etc
- Sports, art and other sponsorships

This guideline shall not apply to:

- Informative materials such as notices or public service announcements, provided they do not include product claims, measures or trade practices relating to prices, margins or discounts;
- A public event where an investigational medicine or allied substance is being discussed.
- Public health awareness campaigns provided they do not name or refer to specific brands.

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4. Requirements for Advertising, Marketing, Promotion, Exhibition, Launch or Discussion of a Medicine and Allied Substance

4.1 General Requirements

- 4.1.1 A person shall not advertise, market, or promote any medicine or allied substance without a Marketing Authorisation issued by the Authority.
- 4.1.2 A medicine or allied substance with a valid Marketing Authorisation issued by the Authority whose annual retention fees have been duly paid may be advertised, marketed or promoted in Zambia. Notwithstanding the aforesaid, a medicine or allied substance shall not be advertised, marketed or promoted without prior written authorisation from the Authority.
- 4.1.3 An application to advertise, market or promote a medicine or allied substance shall be made by a holder of a Marketing Authorisation or appointed local responsible person.
- 4.1.4 An application to exhibit, launch or discuss a medicine or allied substance at a public event shall be made by a holder of a Marketing Authorisation or appointed local responsible person.
- 4.1.5 All advertising, marketing and promotional material shall conform to the product information, including labelling and package insert, as approved in the Marketing Authorisation issued by the Authority.
- 4.1.6 Advertising, marketing and promotional information on safety, efficacy, quality, performance and ingredients shall conform to that which was approved at grant of Marketing Authorisation.
- 4.1.7 Advertising, marketing or promotional material must include the approved name of the medicine or allied substance.
- 4.1.8 Advertisement, marketing or promotional material shall only be published or issued as approved by the Authority.
- 4.1.9 The Marketing Authorisation Holder shall be responsible for information that they issue on their product.
- 4.1.10 Public health programs should obtain authorisation from the Marketing Authorisation Holders for publication of advertisement, marketing or promotional materials.
- 4.1.11 Public health programs campaigns shall be notified to the Authority before publication of advertisement or promotions.



4.2 Submission of an Application

An application shall comprise:

- 4.2.1 A duly completed application form;
 - a) Application for promotion or advertisement - Form I (Appendix 1)
 - b) Application for exhibition, launch or discussion – Form V (Appendix 2)
- 4.2.2 Proof of payment of the prescribed fee;
- 4.2.3 A copy of the proposed advertising, marketing or promotional material as it is to be presented, in electronic format;
- 4.2.4 For audio/visual advertising, marketing or promotional material, a written script of the advert and the audio/visual files in electronic format;
- 4.2.5 Where an advert is in a local language(s), then a script in both the local language(s) and a certified English translation(s) must be submitted;

Note: All application documents shall be in electronic format and submitted online via the online portal on the ZAMRA website.

4.3 Evaluation of an Application

- 4.3.1 The Authority shall, upon receipt of an application, screen the submitted documents for completeness and may request an applicant to submit additional information.
- 4.3.2 The Authority shall, upon receipt of a valid application, evaluate the application and notify the applicant in writing of its decision to approve or reject the application within the timeline stipulated in the Service Charter.
- 4.3.3 Once approved, advertisement, marketing or promotional material shall be assigned a unique identification mark and shall be valid for the period of one year from the date of approval, subject to renewal of Marketing Authorisation and payment of annual retention fees for the product to be advertised, marketed or promoted.
- 4.3.4 A person who wishes to extend the validity of advertisement, marketing or promotion of a product shall be required to submit a new application in the prescribed format upon payment of the prescribed fees.



4.4 Amendment of an Approved Advertisement, Marketing or Promotional Material

- 4.4.1 A person who intends to amend an approved advertisement, marketing or promotional material for a medicine or allied substance shall, using the prescribed form and upon payment of the applicable fees, apply to the Authority.
- 4.4.2 The Authority shall, upon receipt of a valid application, evaluate the application and notify the applicant in writing of its decision to approve or reject the application within the timeline stipulated in the service charter.

4.5 Advertisements, Marketing and Promotions Targeted at the General Public

- 4.5.1 Advertisements, marketing and promotions targeted at the General Public shall:
- Contain information that helps them make rational decisions on use of the medicine or allied substance;
 - Contain warnings and precautions and the need to seek medical attention should the symptoms persist;
 - Not concern narcotic or psychotropic medicine or any other controlled medicine or allied substance;
 - Not involve medicine or allied substance categorised as 'Prescription Only' or 'Pharmacy Only';
 - Not involve a medical device intended to be used by a health practitioner.
 - Not involve a medicine or allied substance for the treatment of a disease or condition listed in **Appendix 3**.
 - Not be presented to suggest that the use of the medicine or allied substance will improve normal good health or vice versa;

4.6 Advertisements, Marketing and Promotions Targeted at Health Practitioners

- 4.6.1 Advertisements, marketing and promotions targeted at Health Practitioners shall:
- Contain information that is reliable, accurate, truthful, informative, balanced, up-to-date and

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- be verifiable;
- b. Indicate limitations for use of the medicine or allied substance, where applicable;
- c. Not contain omissions which may lead to medically unjustifiable use of a medicine or allied substance or give rise to undue risks;
- d. Not, through selection of testimonies or evidence which is not representative of the product effectiveness, make overstated claims or claim that it possesses special properties or qualities which cannot be established.
- e. Only be:
 - i. published in a scientific or medical journal;
 - ii. published in promotional material intended for a health practitioner; or
 - iii. exhibited, launched or considered at a public event where relevant experts are the target audience.

4.7 Claims and Comparisons

- 4.7.1 Content used in Advertising, marketing and promotional material shall be balanced, true and should not mislead or contain any overstated claims, either direct or implied.
- 4.7.2 Advertising, marketing and promotional material shall be legible and clearly communicated.
- 4.7.3 Information presented with the use of visual aids, such as pictures, graphs or tables, etc, shall be presented in such a way as to give a clear, honest, truthful and balanced view of the matters which they deal with, and must not be included unless they are relevant to the claims.
- 4.7.4 The word 'new' shall not be used to describe any product or presentation after twelve months from the date of grant of Marketing Authorisation.
- 4.7.5 An advert, marketing or promotional material must not claim that a product has no side effects, toxic hazards or risks of addiction. The word 'safe' must not be used without qualification.
- 4.7.6 Factual comparative advertising, marketing and promotion of products is acceptable, provided that the claims are entirely truthful and verifiable through scientific evidence.
- 4.7.7 In the case of an allied substance containing a herbal extract, the health claims shall be based on long-standing use or supported by clinical data.



- 4.7.8 The health claims shall not contain information which suggests that a medicine or allied substance is safe or effective for the reason that the medicine or allied substance is natural;

4.8 Prohibitions

- 4.8.1 Advertisements, marketing and Promotional material must not imitate the devices, copy slogans or general layout adopted by other companies, organisations or individuals, in a way that is likely to mislead or confuse the consumer or end user.
- 4.8.2 Products categorised as 'Prescription Only' or 'Pharmacy Only' and medical devices intended to be used by a health professional shall not be advertised to the general public.
- 4.8.3 Advertisements, marketing and promotions should not cause consumers unwarranted anxiety that they are suffering from any ailment nor should it imply that suffering may arise if a consumer fails to respond to the advertisement's claim. Communication which brings fear or distress should not be used.
- 4.8.4 Advertisements, marketing and promotions shall not offer to diagnose, advise, prescribe or treat personally by correspondence.
- 4.8.5 Advertisements, marketing and promotions should not discourage consumers from seeking medical care or advice.
- 4.8.6 Advertisements, marketing and promotions shall not claim, or imply, that a product's effects are guaranteed.
- 4.8.7 Advertisements, marketing and promotions should use language or terminology that does not confuse or mislead the consumer or end user.
- 4.8.8 Advertisements, marketing and promotions should not suggest that the medicine or allied substance has been recommended or endorsed by scientists or health professionals.
- 4.8.9 Advertisements, marketing and promotions should not include a recommendation or endorsement by a person who, because of their social or celebrity status, may encourage consumers to use a medicine or allied substance.
- 4.8.10 Notwithstanding, 4.8.9 shall not apply to advertisements, marketing or promotions involving cosmetics.



- 4.8.11 An advertisement for nutritional supplements should not imply that supplements are:
- a substitute for good nutrition or a balanced diet;
 - in any way superior to or more beneficial than good nutrition or a balanced diet or dietary nutrients or that normal health may be affected by not taking the supplements.
- 4.8.12 Aggressive advertising, marketing or promotion practices that significantly impair, or are likely to impair the consumer's freedom of choice or conduct in relation to the product concerned using harassment, coercion or undue influence is prohibited. This includes the exploitation by the trader of any misfortune or circumstance of such gravity as to impair the consumer's judgment.
- 4.8.13 Advertisements, marketing and promotions shall not be aimed at children and should not be presented during programs, locations, or on materials intended for children as the target audience.
- 4.8.14 Advertising, marketing or promotional material shall not show children using or within reach of a medicine, allied substance or a high-risk medical device without adult supervision.
- 4.8.15 Products used for the treatment of diseases and conditions listed in Appendix 3 shall not be given as samples.
- 4.8.16 Advertisement material intended for the general public shall not contain pictures of the genital organs or other body parts of a private nature. Pictures other than those prohibited may be used on adverts but they must be tasteful and not offensive.
- 4.8.17 An advertisement, marketing or promotion of a product shall not refer, expressly or by implication, to alleviation or cure of any disease or medical condition or disorder.
- 4.8.18 Advertisement, marketing and promotional materials and activities must not be disguised.
- 4.8.19 Market research activities, post-marketing surveillance studies, clinical assessments and any such activities must not be disguised advertisements or promotions, nor should they contain or lead to disparaging comments about competitors or their products.
- 4.8.20 Advertisement, marketing and promotional materials and activities must not be disguised to attract or target children, pregnant women, lactating women or persons with disease conditions listed in **Appendix 3**.

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- 4.8.21 Advertising of medicines and allied substances for the treatment of the diseases and conditions listed in **Appendix 3** is prohibited.
- 4.8.22 No person or business entity should offer incentives to consumers through advertising for any incentive schemes or price discounts.

4.9 Restrictions

- 4.9.1 Medicines and allied substances may be advertised, marketed or promoted except those that are legally prohibited or restricted by any written law.
- 4.9.2 An advertisement, marketing or promotion of a product should not contravene the ethical standards of the health and other professions.
- 4.9.3 A person shall not provide a health practitioner with more than two promotional samples.
- 4.9.4 Subject to 4.9.3, where promotional samples are provided, they shall be in the smallest commercial pack size.
- 4.9.5 Use of health practitioners in advertisements of medicines and allied substances is restricted.
- 4.9.6 Live Presenter Mentions (LPM) are restricted. Notwithstanding, presenters may be permitted to read out advertising, marketing or promotional scripts as approved by the Authority for cosmetics and household chemical substances. The script shall be approved as 'Live-Presenter-Mention (LPM) Advertisement' and may be presented by a person in a studio or any other function. The scripts shall be read out in the format or form in which it was approved without any variations.
- 4.9.7 Reprints of articles in journals must not be provided unsolicited unless the articles have been peer-reviewed (refereed). Where an article that is not peer-reviewed (non-refereed) is requested by a consumer, a copy may be provided on written request, provided that each page is stamped with the text "non-peer-reviewed or non-refereed article".
- 4.9.8 Advertisements, marketing and promotions should be clearly distinguished from editorial material. Care must also be taken with company-sponsored meetings, reports and similar such materials to ensure that they are not disguised advertisements or promotions.
- 4.9.9 Promotional material shall adhere to data protection and copyright laws.



4.10 Samples of a Medicine or Allied Substance

- 4.10.1 Distribution of a sample of medicines to the general public for promotional purposes is prohibited.
- 4.10.2 Distribution of a sample of an allied substance distributed as 'Prescription only' and 'pharmacy only' and a medical device intended to be used by a health practitioner to the general public for promotional purposes is prohibited.
- 4.10.3 A free sample of a medicine or allied substance may be provided on the following conditions:
- a. A medicine or allied substance does not contain a psychotropic or narcotic substance within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, or local laws.
 - b. A medicine or allied substance is not intended for the treatment of a disease or condition listed in **Appendix 3**;
 - c. A sample of a medicine may be provided only to persons qualified to prescribe or supply it;
 - d. A sample of an allied substance distributed as 'Prescription only' or 'pharmacy only' or a medical device intended to be used by a health practitioner may be provided only to persons qualified to prescribe or supply it;
 - e. A sample of an allied substance distributed as 'General Sale' or a medical device intended to be used by a non-health practitioner may be provided to a person who is not qualified to prescribe or supply it;
 - f. A medical sales representative, MAH or LRP may issue, on a one-off basis, not more than two smallest units of a sample to an individual;
 - g. A medical sales representative or MAH or LRP shall keep a record of distribution of a sample. A person receiving a sample shall sign this record to confirm receipt;
 - h. Each sample shall be identical with the smallest presentation on the market;
 - i. Each sample shall be marked indicating that the product is a "Sample" and is "free" or "not



for sale”;

- j. Each sample shall be accompanied by a copy of the Summary of Product Characteristics or Package Insert.

4.11 Requirements for Persons Involved in Marketing and Promotion

- 4.11.1 Medical sales representatives shall be suitably qualified to market or promote a medicine or an allied substance.
- 4.11.2 A medical sales representative in 4.11.1 shall have requisite qualifications by education and training for the product they are to market or promote and be registered or licensed with the relevant professional body.
- 4.11.3 Medical sales representatives shall be given adequate training by the firm which employs them and shall have sufficient scientific knowledge to be able to provide information which is precise and as complete as possible about the medicine and allied substance which they promote.
- 4.11.4 Medical sales representatives shall not market or promote the following categories of medicines or allied substances to a person who is not a health practitioner:
 - a) A medicine or allied substance categorised as ‘Prescription Only’ or ‘Pharmacy Only’;
 - b) A medical device intended to be used by a health practitioner.
 - c) A medicine or allied substance for the treatment of a disease or condition listed in **Appendix 3**.
- 4.11.5 During each visit, medical sales representatives shall provide the persons visited, or have available for them, the current and approved summary of product characteristics of each medicine and allied substances they present.
- 4.11.6 To ensure the continued safety monitoring of medicines and allied substances in use, medical sales representatives shall provide to persons visited, information on the safety monitoring system in place for reporting of adverse events to a medicine or allied substance to the MAH, LRP or the Authority.
- 4.11.7 Persons qualified to prescribe or supply medicines or allied substances must be able to carry out their duties objectively without being influenced by direct or indirect financial inducements.



- 4.11.8 Persons qualified to prescribe or supply medicines or allied substances must have access to a neutral, objective source of information.
- 4.11.9 Where medicines or allied substances are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons.
- 4.11.10 Persons qualified to prescribe or supply medicines or allied substances shall not solicit or accept any inducement prohibited under the above.

5. Suspension and Revocation

- 5.1 A permit to advertise, market or promote a medicine or allied substance may be suspended or revoked by the Authority where the terms and conditions are breached or contravened.

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6. Appendices

Appendix 1: Application for Authority to Advertise or Promote a Medicine or Allied Substance

Form I
(Regulation 4(1))



Medicines and Allied Substances Act, 2013

Act No. 3 of 2013

The Medicines and Allied Substances (Advertising and Promotion) Regulations, 2025

APPLICATION FOR AUTHORITY TO ADVERTISE OR PROMOTE A MEDICINE

PART 1.0 Particulars of the Applicant

Applicant name and address	Name:	
	Physical and Postal Address:	
	Phone:	Fax:
	Email	
Contact Person	Name:	
	Designation:	
	Phone:	Fax:
	Email	
Marketing authorization Holder	Name:	
	Designation:	
	Phone:	Fax:
	Email	

PART 2.0 Particulars of the Products



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Marketing Authorisation Number	
Name of the Medicine	
Name of Manufacturer	

PART 3.0: Details of the Launch or Exhibition, where applicable

Dates (s) and time(s) of launch: _____

Venue: _____

PART 4.0: Attachments

Submit

Submit samples of Art works, audio/visual recordings of the promotional materials, original copies of promotional materials made in English, copies of charts, pictograms or posters or their miniature representation and letter of authorization from the Marketing Authorisation Holder to advertise a medicine.

PART 5.0: 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 ^a**

a) Name:

b) Designation:

c) Signature: d) Date:/...../..... (dd/mm/yyyy)

^a Should be signed by the Contact Person

FOR OFFICIAL USE

Date of Submission:

Application number:

Payment Receipt number:

Application Complete (Proceed for inspection)

Application Deficient (Notify applicant on deficiencies)

OFFICIAL
STAMP

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Appendix 2: Application to Exhibit, launch or discuss a medicine or allied substance at a symposium or public event

Form V
(Regulation 9(1))



The Medicines and Allied Substances Act, 2013

Act No. 3 of 2013

The Medicines and Allied Substances (Advertising and Promotion of) Regulations, 2025

APPLICATION TO EXHIBIT, LAUNCH OR DISCUSS A MEDICINE AT SYMPOSIUM OR PUBLIC EVENT

PART 1.0: PARTICULARS OF THE APPLICANT

Applicant name and address	Name:	
	Physical and Postal Address:	
	Phone:	Fax:
	Email	
Contact Person	Name:	
	Designation:	
	Phone:	Fax:
	Email	
Marketing authorization Holder	Name:	
	Designation:	
	Phone:	Fax:
	Email	

PART 2.0: DETAILS OF THE PUBLIC EVENT

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Name of Event:
Date:
Time of event:
Venue

PART 3: PARTICULARS OF THE PRODUCT

Name of Product	Market Authorisation Number	Promotional Material to be used

PART 4.0: 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 a**

(a) Name:

(b) Designation:

(c) Signature: d) Date:/...../..... (dd/mm/yyyy)

^a Should be signed by the Contact Person

FOR OFFICIAL USE

Date of Submission:

Application number:

Payment Receipt number:

Application Complete (Proceed for inspection)

Application Deficient (Notify applicant on deficiencies)

OFFICIAL
STAMP



Appendix 3: List of restricted diseases and conditions in advertising, marketing and promotion of medicines and allied substances

1. HIV/AIDS	15. Infertility
2. Malaria	16. Epilepsy or fits
3. Tuberculosis	17. Impotency
4. Cancer	18. SAS Cov-2
5. Ebola	19. Hypertension
6. Sexual Dysfunctions	20. Frigidity
7. Blindness	21. Insanity
8. Leprosy	22. Contraception and pregnancy
9. Menstrual disorders	23. Kidney diseases
10. Cataract	24. Diseases affecting viscera
11. Paralysis	25. Sexually transmitted infections
12. Drug addiction	26. Conception and pregnancy
13. Deafness	27. Fibroids
14. Diabetes	28. Emerging pathogens of public and animal health concern