NDA FDA
and Drugs Authority

RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINE FOR CONTROL OF PROMOTION AND ADVERTISEMENT OF MEDICINES, MEDICAL DEVICES AND COSMETICS IN RWANDA

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FOREWORD

Rwanda Food and Drugs Authority is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the missions of Rwanda FDA, especially in its article 8, paragraph 11, whereby the authority is mandated to regulate and analyze information used in the promotion and advertising of regulated products

Considering the provisions of the technical regulation N° CBD/TRG/017 Rev0 governing the promotion and advertisement of regulated products especially in its article 8, paragraph 11, the authority has to issue these guidelines for control of promotion and advertisement of regulated products

Advertisement and promotion of regulated products remains an important means of creating awareness and disseminating information to the public and healthcare professionals. It also provides a means of updating all on the latest advances and availability and rational use of regulated products.

These guidelines will provide the necessary information on the current minimum requirements for authorization to advertise and promote medicines on conventional, alternative, human and veterinary products, medical devices and medicated cosmetics in Rwanda. Therefore, guidelines stipulate, among other things, elements of advertisement and promotion, restrictions therein, basic requirements and the application procedures for obtaining approval to advertise and promote of regulated products

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ACCRONYMES AND ABBREVIATIONS

Rwanda FDA:	Rwanda Food and Drugs Authority
POM:	Prescription Only Medicines for Humans
POM-V:	Prescription Only Medicines Veterinary
Non POMV-V:	Non Priscription Only Medicines Veterinary
SPCs:	Summaries of Product Characteristics.
OTC:	Over The Counter
Authority:	Rwanda Food and Drugs Authority

GLOSSARY

In these guidelines, unless the context otherwise states:

"Advertisement" means a form of communication through the media about products, services or ideas by an identified sponsor which is used to encourage, persuade or manipulate an audience (viewers, readers or listeners) to continue with or take some new action

"**Advertising**" means anything that is aimed or designed to promote the supply, sale or use of a product whether or not for financial gain, and it includes but not limited to written communication materials (for instance a notice, circular, handouts, wrappers, catalogues, bill boards, posters, newspapers, magazines, digital and social media posters or other promotional document) and an audio (records, tapes, radio,) or visual announcement (films, video recordings, television, internet, electronic media, interactive data systems,…).

"Applicant" means a person seeking approval to promote a medicine, medical device or promotion

"Authority" means the Rwanda Food and Drugs Authority, established by the Law No. 003/2018 of 09/02/2018.

"Dispense" in relation to a medicine or poison, means supply a medicine or poison on and in accordance with a prescription duly given by a duly qualified medical practitioner, dentist or veterinary surgeon;

"Medicine" means any substance intended for human or veterinary use, presented in its finished dosage form, that is subject to control by the Authority and includes medicinal product, pharmaceutical product, herbal medicines, veterinary medicine and related substances.

"Product" means medicine, medicinal product, pharmaceutical product, herbal medicines, veterinary medicine or related substances.

"Pharmaceutical products" means any substance capable of preventing, treating human or animal diseases and any other substance intended for administration to a human being or an animal in order to diagnose diseases, restore, correct or carry out modification of organic or mental functions. It also means products used in disinfecting premises in which drugs are manufactured, prepared or stored, cleaning hospitals, equipment and farm houses.

"Drug promotion" means any activity undertaken by any person or with its authority which promotes the prescription, supply, sale or administration of its products.

"Promotional material" means any representation concerning the attributes of a product conveyed by any means whatsoever for the purpose of encouraging the usage of the product.

“Regulated product” means processed foods, pharmaceutical products, vaccines, human and veterinary processed foods and other biological products used in clinical as drugs, food supplements, food fortification, fortified foods, poisonous substances, herbal medicines, medicated cosmetics, medical devices, tobacco and tobacco products.

“Media” means newspaper, magazine, medical/journal, television, radio, the Internet; Out of home, vehicle branding, posters, handbills, cinema, point of sale material; online, digital and social media, any form of projected light and sound recordings or any of such means of communication.

“General public” means any person considered as a client or potential client.

“Medical device” any instrument, machine, appliance, material intended by the manufacturer to be used alone or in combination for the purpose of diagnosis, testing, vaccination, or for cure, surgery human or animal health protection;

“Misleading information” means information that gives a wrong idea or impression

“Healthcare workers” means medically qualified persons, including physicians, dentists, pharmacists, nurses, assistant medical officers and clinical officers, pharmacy technicians, laboratory technicians, laboratory technologists and any other person who in the course of their professional activities may prescribe, supply or administer a drug or herbal drug

“**Herbal medicine”** a pharmaceutical product with a label identifying its dosage form that contains one or more substances of natural origin that are derived from plants;

“Label” means any tag, brand, and mark, pictorial or other descriptive matter written, printed stencilled, marked, embossed or impressed on or attached to a container of any product

“A manufacturer” means a company that carries out operation s such as production, packaging, repackaging, labelling and relabelling of products regulated by Authority

"Medicine" means any medicament or curative or preventive substance, whether proprietary or in the form of a preparation;

"Medicinal substance" means any medicine, product, article or substance which is claimed to be useful for any of the following purposes:

a) treating, preventing or alleviating disease or symptoms of disease;

b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition; or

c) preventing or interfering with the normal operation of a physiological function whether permanently or temporarily and whether by way of terminating, reducing, postponing or increasing or accelerating the operation of the function in human beings or animals;

"**Manufacturer"** means a person or a firm that is involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labelling of drug and herbal drug.

"Medical claim" includes any statement that conveys information about a disease state or the attributes of a product in respect of its therapeutic use that is a use for the purpose of or in connection with;

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

b) restoring, correcting or beneficial modification of organic or mental functions in man or animal; or

c) disinfection in premises in which food and drugs are manufactured, prepared or kept, hospitals, equipment and farm houses;

"Medical representative" means a person expressly employed by a company whose main purpose is to promote the company's products.

"Prescription medicine" means any product required to be dispensed only upon a prescription given by a medical practitioner, dentist or veterinary surgeon or any other person approved by the Minister;

"Promotion" is any communication that attempts to influence people to buy or use the regulated products. It is the publicizing of a product so as to increase public awareness or sales using of audio-visual, oral or written material through advertising, sales promotion, direct marketing publicity, trade shows, promotional meetings, participation in exhibitions, giving samples, personal selling, etc.

"Promotional material" means any representation concerning the attributes of a product conveyed by any means whatever for the purpose of encouraging the usage of a product**.**

1.0. INTRODUCTION

According to the law Nº 003/2018 of 09/02/2018 establishing Rwanda FDA, especially in its article 8, paragraph 11, the Authority is mandated to regulate and analyze information used in the promotion, advertising and marketing of products regulated under this Law and in its article 9 which give the powers of Rwanda FDA is formulate regulations and guidelines for regulating the manufacture, import and export, distribution, sale and use of regulated products under this Law;

These guidelines highlight general conditions and requirements for promoting medicines, medical devices and cosmetics to the public and healthcare professionals, procedures for submission of application to promote regulated products. The guidelines are meant to be used by people in all walks of life, by governments, pharmaceutical industry (manufacturers, wholesalers and retailers), health professionals involved in prescription, dispensing, supply and distribution of medicines, and consumer groups and the media including professional media such as publishers and editors of medical journals and related publications

Control of promotion of medicines, medical devices and cosmetics aims at ensuring that public and healthcare professionals receive the correct information about the products to help them make an informed decision on the choices and use of products. It also include protecting from false, misleading or deceptive promotions that would create erroneous impression regarding products they consume.

1.1. SCOPE

These guidelines apply to the product advertisement by manufacturers, wholesalers, retailer's dealer's applicants and/or anyone wishing to advertise or promote medicines or medical devices and medicated cosmetics in Rwanda. All advertisements, promotional material and information on medicinal products, medical devices and medicated cosmetics available in Rwanda should comply with requirements in order to support and encourage the improvement of pharmaceutical care and promote their rational use. The information thus provided should enable the health care professional and the patient in making rational decisions in the use of medicines

The product advertisement must be aligned with the intended uses (indications), as per its registration. Advertisements refer to any information that can promote the sale or use of the medical products. It can be in any forms or media, including but not limited to:

- Aerial promotions such as on hot air balloons
- Booklets
- Cinema commercials
- Consumer leaflets
- Direct mail materials
- Internet materials, including press releases intended for internet publication
- On-pack statements

- Outdoor advertising, including billboards, advertisements on wall fences and motor vehicles
- Point of sale materials
- Posters
- Print advertisements
- Promotional aids including those used for direct selling activities
- Sales promotions
- Telephone help lines
- Television and radio commercials
- Sports, art and other sponsorships

1.2. PROHIBITIONS

The applicants shall adhere to the general requirements for advertisements of medicinal products, medical devices and medicated cosmetics. He/she shall not be allowed to:

a) advertise an unregistered medicinal products, medical devices and medicated cosmetics.
b) Advertise an unregistered indication of a registered medicinal products, medical devices and medicated cosmetics
c) Make any false or misleading claims or representations.
d) Make unsubstantiated claims.
e) Target advertising material at children under 14 years old.
f) Make claims that mislead by emphasis, contrast or omission with regard to the safety, quality or efficacy of the therapeutic product.
g) Make claims that give rise to any unrealistic expectations with regard to the effectiveness of the therapeutic product.
h) Make claims that cause fear, alarm or distress to the public.
i) Encourage inappropriate or excessive use.
j) Suggest guaranteed results without side effects.
k) Encourage incorrect use or self-treatment of serious diseases and discourage from seeking a medical professional's advice.
l) Falsely claim any endorsement by public authority.
m) Include endorsements or recommendations by any healthcare professional or a person of celebrity, social or professional status.
n) Use the names or logos of the Authority and any of our professional groups.
o) Offer refunds, in full or partial amounts, to users of the product

1.3. GENERAL REQUIREMENTS FOR PROMOTION

The role of advertisement is not only informing, teaching or reminding the consumer of the existence of goods, it creates benefits in consumer minds and secures product loyalty over substitutes and competitors.

a) Language on promotional adverts should be among official languages used in Rwanda simple-to-understand, easily comprehensive and should not bring fear or distress to the public.
b) The applicant may apply for approval of promotional materials before importing them by submitting the mock-up or design to the Authority for review.
c) The content of promotional materials must be designed in such a way that it is clear and that the material or message are in line with the product being advertised. Promotion must present information which is factually correct and those facts should not be exaggerated in any way.
d) Promotion must be consistent with the approved product information. The promotion should be in line with conditions or illness for which it has been registered.
e) Promotions should be done as per the approved adverts. No changes can be made on the approved adverts without approval of the Authority.
f) Public information about planned or ongoing trials in unauthorised indications/ uses is not acceptable.
g) Promotion should be objective, without relying solely on the feelings or opinions of the advertiser and should refer to limitations that were relevant to the claims made for the product.
h) Promotional claims presenting findings from studies as directly relevant to the clinical use of the product may also be considered to exaggerate the benefits of the product, unless data are available to demonstrate the relevance and significance of the findings.
i) Advertisements should be reliable, accurate, up-to-date, truthful, informative, balanced, and capable of substantiation and in good taste.
j) Unsubstantiated claims of superiority over other brands

1.4. SPECIAL REQUIREMENTS

1.4.1. Requirements for promotion of medicines

1.4.1. 1 Conventional and herbal human medicinal products

a) Promotion to the public is not permitted for prescription medicines including narcotic and psychotropic medicines. However the Authority may approve promotion of prescription medicines based on public interest according Ministerial order No 20/35 of 09/0/2015 determining unauthorized of controlled substances classified as narcotics drugs, pyschotropic substances and precursors
b) No Over The Counter (OTC) drug advertisement shall imply that the consumer is suffering or without treatment may suffer more severely from any illness, ailment or disease.
c) It should be clearly indicated in the adverts that a medical consultation or medical diagnosis is necessary before self-treatment.

d) Promotion of any medicines directed to the general public which is likely to lead to the use of a medicine is not allowed further reference in the Ministrial Instruction No 20/4991/DGCS/2021 scpecified in article 3.
e) Advertising of medicinal products shall reflect an overall attitude of caution in relation to drug usage, with emphasis on rational use of medicines. It shall provide sufficient and balanced information to permit assessment of risk against the benefits.
f) Promotion should not state or imply that a product is "safe", is "100% safe" has "no side effects" or " their use will not cause harm". No advertisement shall contain words such as magic, miracle or mystical;"drug of choice" exotic descriptions such as 'super potency' or such other words as to induce the daily and continuous use of the product.
g) Promotional information available for self medication should not in any way put the vulnerable patient groups at risk e.g use of medicines during pregnacy.
h) No advertisement for drugs shall contain any price, offers of gifts, competition or refund of money to dissatified consumers.
i) Advertisement for vitamins should not imply that vitamin supplements as substitute for good nutrition or balanced diet
j) Promotion should be designed to ensure that prescribers are not misled by promotional claims in adverts which suggests that a particular medicine is safer than an alternative medicine unless this is supported by evidence.
k) Promotional materials / adverts for dissemination to healthcare professionals only should be clearly stated in the materials or adverts "for healthcare professionals only".
l) Storage of medicines within view of public area (e.g. on display behind a pharmacy counter) should not be considered to be an advert provided that no product (s) is being promoted. This practice is acceptable as long as no attempt is made to make any product (s) more prominent than the others. However, for safety reasons it is considered good practice for all POMs to remain out of the sight and reach of clients (i.e must be stored behind the sales counter and must not be available for self selection).

1.4.1.2 Traditional medicines

Traditional medicines allowed to be promoted for medicined purposes are only those which have been registered by the Authority. Specific requirements for promotional of these medicines are as follows:

a) Promotion should be done only after being issued with a written approval from Authority.
b) Promotion should not contain an offer to treat any person, or to prescribe any remedy for its treatment, or to give any advice in connections with the treatment of the diseases or conditions such as HIV/AIDS, Blindness; Cancer; Cataract; Drug addiction; Deafness;Diabetes; Epilepsy or fits; Hypertension; Insanity; Kidney disease; Leprosy;

Mentrual disorders; Parlysis; Tuberculosis; Sexual Dysfunctions; Infertility; Importency; Frigidity; Conception and Pregnancy.

c) Promotional claims such as "clinically proven" or "effective in" are not acceptable since the registration of the products are principally based exclusively on long-standing use.
d) Indications mus be true, valid and not misleading and should nt lead to unsafe or inappropriate use of the product. Indication can be based on evidence of traditional use of substance or product,
e) Promotional claims should be in line with the approved indications(s). Where the indication states "traditionally used for" or similar wording, this information must be stated in the promotion.
f) General health claims to illustrate the kind of efficacy claims may be used based on traditional/ long-standing use, with documented evidence in the approved product information. Examples include; use as a liver tonic or to support liver function; for energy and general health maintenance; helps to maintain healthy vision; helps to support urinary tract function; promotes joint mobility; promotes vitality; promotes healthy hair &skin etc.
g) Promotional claims that a product is "organic"may only be made for products that have been registered as such.
h) Promotion should not suggest that the safety and efficacy of the product is due to it being "natural"
i) Promotion of traditional medicine should not contain a disclaimer stating that 'efficacy' of this product has been proven by Rwanda FDA".
j) Promotional should contain a clear and legible invitation to "read carefully the instructions on the leaflet enclosed" in the package or on the label as the case may be.

1.4.2 Veterinary medicines

Veterinary medicines are grouped as veterinary prescription medicines (POM-V) and veterinary non priscription medicines (Non POMV-V). Specific requirements for promotion of veterinary medicinary are as follows:

a) POM-V should not be advertised to the general public.
b) Promotional adverts for POM-V including veterinary medicines containing psychotropic drugs or narcotics and all antimicrobial products may only be promoted or featured in public a cautions aimed to pharmacists and veterinary healthcare professionals which include veterinary, para professionals and para professionals assistants.
c) Promotion of antimicrobial products should not encourage unnecessary use of these medicines and all promotional adverts should contain a strap line indicating that the prescription and administration of the product should be in accordance with the responsible use of antimicrobials.

d) Educational information designed to give a balanced overview of the disease and all available treatments may be made available to the general public providing that products or brand names are not mentioned and all other promotion restrictions are adhered to.
e) Storage of medicine within view of a public area (e.g. on display behind a veterinary pharmacy counter) should not be considered to be an advert provided that no product (s) is being promoted. This practice is acceptable as long as no attempt is made to make any products more prominent than the others. However, for safety reasons it is considered good practice for all POMs to remain out of the sight and reach of clients unless they are actually being used on the animal as part of the consultation.
f) Promotion of any human medicine for administration to an animal is restricted even if there is no equivalent veterinary medicine

1.4.3 Requirements for promotion of medical devices

a) Promotion should not directly or indirectly suggest that the medical device can prevent, retard or reverse the physiological changes and degenerative conditions brought about by or associated with ageing.
b) Promotion should not make use of names, initials, logos and/ or trade marks of any company or institution without written permission from the concerned company or institution.
c) Medical devices classified as "Professional Use Only" should only be allowed to be promoted to healthcare professionals.
d) Promotion should not give any implication that the medical advice can induce sexual virility or they are effective in treating sexual weakness or sexual excess and conditions such as premature ejaculation and erectile dysfunction.
e) Promotion should not contain any claim, statement or implication that the medical device is infallible, unfailing, magical miraculous, or that it is a certain, guaranted; sure cure or compete cures
f) Promotion shall not expressly or implicity claim, indicate or suggest that the medical device will prevent, alleviate or cure any disease or conditions
g) Promotion to the general public should not directly or indirectly encourage indiscriminate, unneccesary or exclussive use of the medical device
h) Testimonials featured in advertisements should reflect the typical experience of an average user of a medical device.
i) Promotion to the public should not give the impression of advice or support from healthcare providers, i.e. visual and/or audio presentation of healthcare professionals.

1.4.4 Requirements for promotion of cosmetics

a) No person or media shall advertise any cosmetic in the print, electronic media including internet or by any means should unless such advertisement has been approved by the Authority.

b) Advertisement and promotion material that are subject to the guidelines include but limited to innternet material, including press releases intended for internet publication, publication, print advertisements, promotional aids including those used for direct selling activities, sales promotions, telephone help lines television and radio commercials, sports art and other sponsorships.
c) Advertisements shall not contain or refer to any testimonial or endorsement unless it is genuine and related to the personal experience over a reasonable period or time of the person giving it.
d) Advertisements should contain information that is reliable, accurate, truthful, informative, balanced, up to date, and capable of substantiation and in good taste. They should not contain misleading or unverifiable statements or omissions likely to induce unjustifiable use or give rise to undue risks.
e) Advertisement should not induce fear on the part of the viewer or listener that he/ her is suffering and without the use of cosmetic product may worsen the condition
f) Claims on cosmetics shall not imply actions that are normally considered therapeutics in nature
g) Promotional claims should take into consideration that cosmetics product typically have effects that are not permanent , and have to be used regularly to maintain their effects.
h) Promotional claims can be softened or made less functional and more cosmotic in nature by the use of modifiers. For example: claim for removing all oil from the skin, can be softened as “helps to remove oil skin” or “reduces the shine of oily skin or suitable for oil skin” or “reduce the shine of oily skin” or “ makes your skin feel les oily”

2.0. TARGETED AUDIENCE IN ADVERTISEMENT AND PROMOTION

2.1 **Advertising Information to the Healthcare Workers**

A written advertisement for medicines should contain the follwing elements

a) Trade/ Brand name or proprietary name,
b) A quantitative listing of all active ingradient(s) using either approved generic name or international Non-proprietary Name (INN) of medicine
c) An accurate statement of the dosage and strength
d) Daily dose, frequency of administration
e) Route or method of administration
f) Major indication(s) for use;
g) Adequate warnings(caution side effects, interactions)

h) Major precautions, contra-indications and warnings;

Name and address of manufacturer or packaging company. If an imported drug, the name and address of the local packing company or distributor must appear on the label in such a manner as to identify the relationship between the packing company or distributor with such drug.

2.2 **Advertisement to the general public**

1) Advertisement targeted to the general public must contain the following:
   a) The generic name of a drug, brand name/trade name of the drug
   b) name(s) of the active ingredient(s) using international non-proprietary names (INN)
   c) approved major indication(s) for use
   d) major precautions, contra-indications and warnings
   e) name and address of manufacturer
   f) dosage regimen
   g) phrase "If symptoms persist seek medical advice" or a similar meaning phrase

2) Advertisement to the general public shall take into consideration the following:
   a) Help people to make an informed decision on the choice and use of drugs determined to be legally available without a prescription.
   b) Take account of people's legitimate desire for information regarding their health.
   c) Not take undue advantage of people's concern for their health

2.3 **Activities that do not form advertisement and promotion**

The following activities do not form advertisement and promotion practices:

a) replies made in response to individual enquiries from healthcare workers or employees in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature,
b) factual, accurate, informative announcements and reference material concerning licensed medicines and relating, for example, to pack changes(color,design), adverse reaction warnings, trade catalogues(for medical devices only) and price lists, provided they include no product claims.
c) Statements relating to human health or diseases provided there is no reference, either direct or indirect, to specific products.
d) An advertisement that over-dramatizes any symptoms by way of drawing a picture

3.0. MODE OF ADVERTISEMENT AND PROMOTION

Any activity undertaken in the different methods provided hereunder shall constitue the medicines, medical devices and cosmetics promotion. Therefore it shall be used after approval of Authority:

a) **Still**

Includes any promotional adverts in print media such as magazines, news papers, journals, diaries, flyers, brochures, billboards, posters, branding on vehicles, buildings, benches and other print publications. A promotional aid (note pads, calendars and other such items) shall be limited to bear names of products currently registered in Rwanda.

b) **Light and sound**

Includes any promotional adverts with light and sound effects, such as broadcast over radio, radio cassettes or any audio, television, cinema advertisements and videos.

c) **web based**

Includes any promotional adverts on websites. Promotion of prescription medicines are acceptable only on websites whose nature and content are directed to healthcare professionals. Sections of a website aimed at airing such adverts should ideally be access restricted. Where an information is presented as a linked page on an internet website, the link should be clearly visible.

d) **Sales promotion**

This is any activity with the purpose of introducting, publicising or promoting the sale of a product

e) **Promotion Samples**

- ✔ There should be no sale or supply of samples of medicines or medical devices to any member of the public for promotion purposes.
- ✔ Samples of medicines (except for traditional medicines) and medical devices may only be supplied as free samples to qualified prescribers or pharmacists for the purpose of promotion.
- ✔ The free samples provided by medical representatives should be labelled “physician sample not for sale”.
- ✔ There are no restrictions applicable to cosmetics with regard to provision of this section.

f) **Symposia and other meetings**

All meetings including workshops, conferences, seminars symposia and exhibitions that are organized or sponsored by any company or under its control targeting the healthcare professionals,

or any other person for the purpose of promoting medicines, medical devices or cosmetics or its launching should first obtain approval from Authority. The following procedures should be made when filling in applications for promotional meetings :

- ✔ Applications should be made by filling in the application form as prescribed in **Annex I** and submitting to the Authority not less than 2 weeks before the meeting.
- ✔ The application should be accompanied by the proof of payment for fees prescribed in regulations no CBD/TRG/004 related to regulatory service tariff/fees and fines; and the samples of all materials or products to be used in the meeting for promotional activities.
- ✔ Presentation at symposia or seminars shall be factual, accurate, without omission and not biased towards any particular company's products.
- ✔ Sales of medicines during such meetings or trade where regulated products is exhibited is prohibited.

g) **Promotion in public health programme/campaigns**

- ✔ Campaigns relating to medicines, medical devices or cosmetics that are directed to the general public with a view of providing information, promoting awareness or education about a particular condition or disease are encouraged. But, care must be taken to ensure that the information provided is correct as per this guideline requirements.
- ✔ Public health programmes such as government controlled programmes (vaccination &malaria campaigns etc) that have been approved by the responsible ministry are required to obtain an approval letter from the Authority

3.1 Requirements for promotion & advertisement applications

a) Application letter addressed to Authority
b) Applications for approval of promotional materials for medicines, medical devices , cosmetics shall be made by submitting a dully filled application form attached as **Annex** Ⅲ accompanied with prescribed information as detailed in these guidelines.
c) Samples of Promotional materials to be aired in one CD-R copy or printed scripts of the final adverts with respect to media to be used. **Note that**: documented such as video clips should be viewable via Windows Media Player.
d) Proof of sciencific evidence for claimed information
e) Samples (if applicable) of the final package and ready for the market
f) Applications shall be accompanied by the following:
   - ✔ Proof of up-to-date registration of the company that wishes to advertise;

- ✔ Proof of up-to-date registration of the product to be advertised;

g) Certified copies of degrees of qualified personnel in areas of medicine who will promote and advertese the products or who approved the message at company level.
h) The proof of payment of prescribed fees under Regulations no CBD/TRG/004 related to regulatory service tariff/fees and fines may be paid directly to the Authority

4.0. STAKEHOLDERS RESPONSIBILITIES

In order to effectively execute its functions including management and control of product promotions, Authority has to work in close cooperation and collaboration with all stakeholders. The various roles and responsiblities of different Authority stakeholders in line with promotion of regulated products as follows:

4.1 Medical and pharmaceutical representatives

All dealers of medicinal products, medical devices and medicated cosmetics include manufacturers, importers and distributors, suppliers, wholesalers and retailers. Generally, dealers are responsible to ensure that their products comply with quality, safety and efficacy standards and are officially authorised by the Authority to be marketed in Rwanda before subjecting them to any promotional activity. The manufacturers and distributors should submit applications for authorization of their medical representatives to the Authority.

This will evaluate the applications and issue a permit for medical representatives once the prerequisite conditions have been met. The manufacturer and/or distributor will be responsible for the statements and activities of their medical representatives. Any change of employment by a medical representative must be reported to the Authority, and a new permit issued with respect to the new employer.

4.2 Qualification of medical representatives

The medical representative shall possess minimum qualification of Diploma (A1 or A2) in medical science (Pharmaceutical, Medicine and Surgery, Veterinary medicine, Nursing and Midwife, Dental therapy/Surgery, Clinical medicine, Anaesthesia, Ophtalmology, Laboratory, Bio-Medical Engineering, Clinical psychology, Public health,…) or life sciences (Bio-Technology, Biology, Food Science, Chemistry, Microbiology,…) veterinary or public health from recognized institution with relevant experience and/or trainings in matters related to medicines.

In preparing promotional adverts, dealers are obliged to ensure that the information provided about their respective products are correct and presented objectively to encourage their rational use. The information provided must comply with the Authority Regulations on product promotions.

Dealers are also responsible to report to the Authority any contraventions and/or all defaulters of the laws and regulations and be ready to collaborate and cooperate with Authority in sharing information relating to quality, safety and efficacy of medicines,medicinal devices and cosmetics.

4.3 Local Government Authorities and Law enforcers

Local Government Authorities and Law enforcers plays the roles and responsibilities to enforce the of laws and to sensitize their employees to voluntarily enforce the services and its regulations including one for control of medicines, medical devices and cosmetics promotion in this case.

4.4 Healthcare Professionals

Healthcare professionals are among important players in medicines, medical devices and cosmetics promotions. They play two counter roles; promoters as well as persons to whom promotions are directed. Therefore healthcare professionals are responsibles to:

a) Lawfully participate in product as well as health promotion campaigns to influence rational use and raise awareness of heath issues and disease prevention.
b) Report to the Authority any contraventions and/or all defauters of the laws especially dealers who deliberately give out exaggerated or misleading information about quality, safety and efficacy of medicines, medical devices and cosmetics.

4.5 Media

Media plays a great role in emphasizing voluntary compliance to the existing laws and regulations though public education. The role of media in advocating these requirements for product promotion is :

a) To convey the right information about regulated products and particularly the DOs and DON'Ts in terms of promoting and advertising medicines, medical devices and cosmetics and educate the public accordingly;
b) To voluntarly comply with the requirements of the Authority, and respective regulations and guidelines for control of product promotion;
c) To report to the Authority any contraventions and/or all defaulters of the laws especially dealers who deliberately give out exaggerations or misleading information about quality, safety and efficacy of medicines, medical devices and cosmetics;
d) To reject airing any promotional adverts from dealers which do not have approval from the Authority;
e) To give constructive comments and recommendations on how to effectively and efficiently control regulated product promotions;

4.6 General Public

All promotions and advertisements prepared by dealers are made in a way to purseade community members to make choice of buying/ using them. Hence, the general public is a very important

category of stakeholders in ensuring that dealers of medicines, medical devices and cosmetics comply to laws and promotion regulations.

The general public is thus obliged to:

a) Fetch the right/ correct information from Authority on the quality safety and efficacy of medicines, medical devices and cosmetics.
b) Require the Authority to always provide updated information regulated products.
c) Report to the Authority any promotion or advertisement which has been forbidden and/or whose information is suspected to be exaggerated or misleading information about quality, safety and efficacy of medicines, medical devices and cosmetics.

5.0. COMPLAINTS REGARDING PROMOTED PRODUCTS

The Authority is particularly keen to receive complaints where promotional adverts may have an adverse impact to public health. It will investigate complaints received from anyone who has seen promotion advert for a medicine, medical devices or cosmetics that in his/her view is misleading or otherwise fails to comply with the legal requirements.

The following is the procedure for logging complaints regarding promoted products:

a) Complaints on advertised or promoted products identified under these guidelines shall can be made to the Authority in the prescribed form attached as **Annex II.** The form can be obtained from Rwanda FDA headquaters or through the Rwanda FDA website
b) Complaint forms that have not been completed and signed will not be processed.
c) A submitted complaint should have detailed of when and where the promotion advert was seen and if possible a copy of the advertisement, together with detailed of the concerns about the advertisement should be attached.
d) The Authority will complete the investigation within 30 days. This time may be extended when statutory action is taken. Should the investigation take longer, the complainant will be updated on progress.
e) When closing the case the Authority will provide the complainant with details of the outcome

ENDORSEMENT OF THE GUIDELINES

	Author	**Authorized by**	**Approved by**
Title	Division Manager of Pharmacovigilance & Food Safety Monitoring	Head of Food & Drugs Inspections & Safety Monitoring Department	Director General
Names	**NTIRENGANYA Lazare**	**GISAGARA Alex**	**Dr Charles KARANGWA**
Signature			

Date			

Annex 1: Application Form (CTA)

1. **Applicant Particulars**

Name of applicant:..... .....
Address: .....
Contact person: .....E-mail: .....
Telephone Number: ..... Fax Number: .....

2. **Type of meetings (tick)**

[ ] Workshop
[ ] Conferences
[ ] Seminar
[ ] Symposia
[ ] Exhibitions

3. **Responsible Person Information**

3.1 Name of person / company responsible for event.....

3.2 Address .....

3.3 Telephone Number Fax (if applicable) Email (if application)
.....

4. **Location Information**

4.1 Name of premises where event is to be held .....

4.2 Plot No./ Street/ Municipal/ Town/ City/ Region .....

5. Dates and Times of Event

Start Date/ Time .....

End Date/ Time
(a.m / p.m.) Room Name / Area / Location .....

6. **Product (s) promoted (attach list)**

Product category (please tick the appropriate box**)**
Human Medicine [ ] Veterinary Medicine [ ] Herbal Medicines [ ] Traditional Medicine [ ] Medical Device [ ] Cosmetic [ ] other [ ]splease specify.....

Product Name(s):
.....

Registration number:
.....
Name of registration:
.....
Type of Advertisement:
.....
Type of material: (please tick the appropriate box)
Poster [ ] Leaflet[ ] Cinema [ ] Outdoor/ billboard [ ] In /On Public Transport[ ]
Magazines/ Newspaper [ ] Litterature [ ] Radio [ ] Television [ ]
Other [ ] please specify .....

This form shall be accompanied by:
NB: Please tick or mark X on Checklist

[ ] A copy of the proposed advert (Script, Audio tape, CD, VCD, DVD, Video casette.)
[ ] Current indications of use as indicated on Certificate of Registration (where applicable)
[ ] Copy of any research/ surveys/ data metioned in advertisement
(Note- further evidence to be provided if requested).
[ ] Copy of previous approval (if the advert is a reminder)
[ ] Copy of approval for the use of a restricted / prohibited claim (if applicable).
[ ] Application fee.

Applicant Declaration

I, ...declare that the information contained within this apllication is true and correct.
Signed: .....
Date: .....

ANNEX 2: Complaint form

1.0 COMPLAINANT / REPORTER DETAILS (optional)	
1.1 Name of the person / company / institution	
1.2 Address	
1.3 Email	
1.4 Telephone Number	
2.0 PRODUCT DETAILS	
Product Type: (tick)	
2.1 Human medicine	
2.2 Veterinary Medicine	
2.3 Herbal Medicine	
2.4 Traditional Medicine	
2.5 Medical Device	
2.6 Cosmetic	
2.7 Others (please specify)	
3.0 ADVERTISEMENT TYPE	
3.1 Magazine/ Newspaper	
3.2 Radio	
3.3 Cinema	
3.4 Outdoor/ billboard/ shopping mall	
3.5 Television	
3.6 In/ on public transport	
3.7 Others- please specify	
4.0 SUPPORTING INFORMATION / DOCUMENTS	
4.1 Copy of the advertisement (if applicable)	
4.2 When and where it appeared	
4.3 Reasons for your concern over the advertising e.g. what you consider is wrong with it.	
4.4 Advertising complaints related to product unauthorised (Not registered) by Authority	Yes:..... No:.....
4.5 A copy of any information regarding any communication that you have been involved in with the advertiser prior to complaining to the Authority	Yes:..... No:.....
Signature of complainant: **.....**	**Date :** **.....**