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TANZANIA FOOD AND DRUGS AUTHORITY

GUIDELINES FOR CONTROL OF PROMOTION AND ADVERTISEMENT OF MEDICINES, MEDICAL DEVICES AND COSMETICS IN TANZANIA

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Table of contents

Abbreviations

DANIDA	-	Danish International Development Agency
PHLB	-	Private Health Laboratories Board
POM	-	Prescription Only Medicines for humans
POM-V	-	Prescription Only Medicines for veterinary
RALGAs	-	Regional Administration and Local Goverment Authorities
TAPI	-	Tanzania Association of Pharmaceutical Importers
TFDA	-	Tanzania Food and Drugs Authority
TFDCA	-	Tanzania Food, Drugs and Cosmetics Act
TPMA	-	Tanzania Pharmaceutiacal Manufacturers' Association

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Foreword

Promotion of medicines, medical devices and cosmetics remains an important means of creating awareness and disseminating information to healthcare professionals and the general public. It provides a means of updating the public on latest advances and rational use of products. Promotion can also, if not carried out correctly, pass the wrong information and in turn affect public health. Unethical promotions that are based on false and exaggerated claims can also affect the healths of consumers.

Recently, in Tanzania there has been a notable increase on the number of advertisements and promotional activities for medicines (including herbal and traditional medicines), medical devices and cosmetics through various media such as television, radio and news papers. Moreover, unauthorized promotions particularly of traditional medicines by unqualified personnel have been commonly noted at various places including bus stands and in moving vehicles contrary to the laws and regulations. This poses a health threat to the potential users as such advertisements contain misleading information on safety, quality and efficacy of products.

These Guidelines for Promotion of Medicines, Medical Devices and Cosmetics have been developed to provide minimum standards for advertisement and promotion of medicines, medical devices and cosmetics in Tanzania. The guidelines explains among other things, provisions and requirements for advertisement and promotion and the application procedures for obtaining approval to advertise and promote regulated products.

It is my sincere hope that these guidelines will serve as an important tool for every dealer of medicines, medical devices and cosmetics who is engaged in promotional activities in Tanzania.

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Introduction

Tanzania Food and Drugs Authority (TFDA) is empowered under Section 5 of the Tanzania Food, Drugs and Cosmetics Act, 2003 to regulate all matters relating to quality and safety of food, medicines, cosmetics and medical devices including control of product promotion.

The legal basis for the control of product promotion is contained in Section 98(2) of the Tanzania Food, Drugs and Cosmetics Act, 2003. The section requires no person or institution to engage in any kind of promotional activities of regulated products except after obtaining a written approval from TFDA.

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

It is from these legal requirements that these Guidelines for Promotion of Medicines, Medical Devices and Cosmetics have been prepared. The Guidelines are intended to provide guidance to manufacturers, wholesale and retail dealers of medicines, medical devices and cosmetics, and any other stakeholders who are involved or wishing to be involved in promotional activities in Tanzania to abide to existing laws and comply with promotion standards. The criteria are applicable to both prescription and non-prescription medicines both for human and veterinary, medical devices and cosmetics. It also applies to traditional, herbal and other alternative medicines and any other products promoted as medicines.

The Guidelines highlights general conditions and requirements for promoting medicines, medical devices and cosmetics to the public and health care professionals, procedures for submission of application to promote regulated products and general promotion guidance including type and category of products which can be promoted or not, language to be used and necessary fees to be payable for evaluation of promotional materials before approval is granted. Moreover, the guidelines outlines the conditions for interested dealers of regulated products to comply in order to ensure sustainable promotion of their products, and stakeholder's responsibilities on all matters pertaining to promotion of medicines, medical devices and cosmetics.

Dealers of medicines, medical devices and cosmetics and specifically those involved or wishing to be involved in any of the above activities are required to abide to these requirements. It is an offence for any person or institution to breach any of the

requirements of these Guidelines. Should there be a breach of conduct immediate warnings, sanctions and penalties will be imposed as provided in TFDC Act.

In developing these guidelines, guidance documents were referred from:-

a. Guidelines for Advertisement and Promotion of Medicines and Medical Devices in Kenya, First Edition-April, 2012;
b. The Blue Guide Advertising and Promotion of Medicines in the UK Medicines and Healthcare Products Regulatory Agency Third Edition August, 2012
c. A Guide on Advertisements and Sales Promotion of Medicinal Products December, 2010 from Health Sciences Authority-Singapore
d. Veterinary Medicines (VMD) Directorate Assuring the Safety, Quality and Efficacy of Veterinary Medicines, Guidance Note No. 4, Control of Advertising, July 2013
e. Other TFDA Guidelines related to medicines, medical devices and cosmetics.

These guidelines should neither be taken as a complete or definitive statement of the law nor replace or constitute formal decisions of the Authority.

Definition of terms

For the purpose of these guidelines, the following phrases are defined as follows:

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

"Act" means the Tanzania Food, Drugs and Cosmetics Act , Cap 219

"**Advertisement"** 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 a notice, circular, label wrapper or other document, and an announcement made orally or by means of producing or transmitting light or sound.

"Authority" means the Tanzania Food and Drugs Authority established under Section 4(1) of the Act.

"**Cosmetics**" means any article intended to be used by means of rubbing, pouring, steaming, sprinkling, spraying on or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and includes any article intended for use as component of a cosmetic; such articles exclude articles intended besides the above purposes for use in the diagnosis, treatment or prevention of diseases and those intended to affect the structure or any function of the body.

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

"General public" means a person other than healthcare workers.

"**General sale medicine**" means any medicine whose use does not need the direction or prescription by a medical practitioner, dentist or veterinarian.

"Healthcare professional" In case of human medicines includes members of the medical, dental, pharmacy and nursing profession and any other person who in the course of their professional activities may prescribe, supply or administer a medicines or herbal medicines and incase of veterinary medicines it includes veterinarian.

"Herbal medicine" means a medicinal product that contains active ingredients one or more natural substances that are derived from plants to which may be added natural substances of animal or mineral origin.

"Manufacture" means any process carried out in the course of making a product or and includes packaging, blending, mixing assembling, distillation, processing, changing of form or application of any chemical or physical process in the preparation of a medicinal substance or product; but does not include dissolving or dispensing the product by diluting or mixing it with some other substances used as a vehicle for administration.

"Manufacturer" means the natural or legal person or a firm that is involved in the production, preparation, processing, compounding, formulating, filling, refining, transformation, packing, packaging, re-packaging and labelling of medicine, medical device or cosmetic.

"**Medicine**" which also include traditional medicine and herbal medicine means drug or any substance or mixture of substances manufactured, sold or presented for use in:-

a. the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnon-nal 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 device" means an instrument, apparatus, implement, medical equipment, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, which is:-

a. recognized in the Official National Formulary, or Pharmacopoeia or any supplement to them;
b. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals or;
c. intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within the body of man or other animals and which is not dependent upon being metabolised for the achievement of any of its principle intended purposes.

"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; should be removed

"Medical representative" means a person expressly employed by a company whose main purpose is to promote the company's products as permitted by the board through issue of a permit.

"narcotic" means any of the substances natural or synthetic referred to in the Single Convention on Narcotic Drugs of 1961 intended for medical and scientific purposes.

"psychotropic" means any of the substances natural or synthetic or any salt or preparation of such substance or material referred to in the Single Convention on Psychotropic Substances of 1971 intended for medical and scientific purposes.

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

"Product" means a medicine, medical device or cosmetic.

"promotion means"

a) advertising;
b) the activities of representatives including detail aids and other printed material used by representative;
c) the supply of samples;
d) the provision of inducement to prescribe, dispense, supply, administer, recommend or buy products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
e) the provision of hospitality for promotional meetings;
f) the sponsorship of promotional meetings;
g) the sponsorship of scientific meetings including payment of travelling and accommodation expenses in connection therewith;
h) the provision of information to the general public either directly or indirectly;

i) all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, radio, television, internet, electronic media, interactive data systems and the like.

"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.

"Traditional medicine" means any product used in Tanzania local systems of therapeutics used in diagnosing, preventing or eliminating a physical, mental or social disease and which may rely exclusively on past experience and observation handled down from one generation to another orally or in writing.

1. GENERAL REQUIREMENTS

Promotion of products regulated by the Authority must comply with requirements prescribed in the Tanzania Food, Drugs and Cosmetics Act, Cap. 219 and respective Regulations. Section 98(2) of the Act prohibits promotion of medicines, medical devices and cosmetics except and after getting a written approval from the Authority. The general requirements for promotion of these products are as follows:-

a) Products should not be promoted unless they are registered or authorized by the Authority.

b) Language to be used on promotional adverts should be either English or Swahili or both, simple-to-understand, easily comprehensible and should not bring fear or distress to the public.

c) Promotion of products should 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 unauthorized indications/uses is not acceptable.

g) Promotion must encourage the correct and proper use of relevant products.

h) Promotion that includes data, trials or studies that are not presented accurately or in context would be considered as exaggeration of the properties of a product.

i) 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.

j) 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.

k) 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".

l) Promotion which refers in improper, alarming or misleading terms to claims of recovery are not allowed.

m) Promotion should not suggest that one product is better than (or equivalent to) another identifiable treatment or product, or that the effects of taking it are guaranteed.

n) Promotion shall not refer to the Act or contain any statement which expressly or implicitly suggests that the use of the product is endorsed by the Authority.

o) Promotion should not in any way discourage the public from seeking the advice of a healthcare provider.

p) Promotion should not bring public impression that their health can be enhanced by taking a product or that health could be affected by not taking the product.

q) Promotion of products to the public in open markets, bus stands and moving vehicles such as buses or any other public transport is not allowed unless approved by the Authority.

r) The displaying of a poster for a specific product in a public place, e.g. at hospitals, clinics, shops or where else would be considered as promotional material aimed at the general public and is therefore considered a breach of the advertising restrictions under these guidelines.

2. SPECIFIC REQUIREMENTS

2.1 REQUIREMENTS FOR PROMOTION OF MEDICINES

Medicines include human medicines (categorized as conventional medicines, herbal medicines and traditional medicines) and veterinary medicines.

2.1.1 Human medicines

2.1.1.1 Conventional and herbal medicines

Medicines in this group are divided into prescription medicines and non-prescription medicines. Detailed particulars to be included in the adverts are prescribed in Regulations 8(1) and 10(1) of the Tanzania Food, Drugs and Cosmetics (Control of Drugs and Herbal Drugs Promotions), Regulations 2010.

In addition to general requirements, specific requirements for promotion of conventional and herbal medicines are as follows:-

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.

b) Promotion of any medicines directed to the general public which is likely to lead to the use of a prescription medicine is not allowed.

c) Promotional information available for self-medication should not in any way put the vulnerable patient groups at risk e.g use of medicines during pregnancy.

d) Promotional claims which refer to the tolerability of a product should be factual and based on the available evidence from clinical trials and extensive post marketing surveillance.

e) 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.

f) Promotional materials/adverts for dissemination to health care professionals only should be clearly stated in the materials or adverts "for health care professionals only".

g) It should be clearly indicated in the adverts that a medical consultation or medical diagnosis is necessary before self-treatment.

h) Storage of medicines within view of a 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).

2.1.1.2 Traditional medicines

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

a) Promotion should be done only after being issued with a written approval from the 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 connection 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 diseases; Leprosy; Menstrual disorders; Paralysis; Tuberculosis; Sexual Dysfunctions; Infertility; Impotency; Frigidity; Conception and Pregnancy.

c) Promotional claims such as "clinically proven" or "effective in" are not acceptable since the registration of products are principally based exclusively on long-standing use.

d) Promotional claims should be in line with the approved indication(s). Where the indication states "traditionally used for" or similar wording, this information must be stated in the promotion.

e) Efficacy claims are not allowed for serious medical diseases, disorders and conditions, including osteoporosis, insomnia, hepatitis, thyroid disorders, heart or cardiovascular diseases, genetic disorders, infectious diseases, sexually transmitted diseases, etc.

f) General health claims to illustrate the kind of efficacy claims may be used based on traditional/long-standing use, as documented 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 medicines should not contain a disclaimer stating that *'Efficacy'* of this product has been proved by TFDA".

j) Promotion of more than one product with similar branding, specifically if the other products are not medicines should be done very carefully to avoid causing confusion, especially where there is a potential risk to public health. For example, where one product may be indicated for children whilst the other is not.

k) Promotion 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.

l) Promotion should not give the impression that a medical consultation or surgical operation is unnecessary, for example by offering a diagnosis or suggesting treatment by post, electronic communication or telephone. Nor should it suggest that health can be enhanced by taking a medicine or that health could be affected by not taking the medicinal product.

m) Promotion should not lead to an erroneous belief of any nature about the product. In particular to the potential benefits or possible risks of a product.

2.1.2 Veterinary Medicines

Veterinary medicines are grouped as veterinary prescription medicines (POM-V) and veterinary non-prescription medicines (Non POM-V). Specific requirements for promotion of veterinary medicines 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 publications aimed to pharmacists and veterinary

health care professionals which include veterarians, paraprofessionals and paraprofessional 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 product or brand names are not mentioned and all other promotion restrictions are adhered to.

e) Storage of medicines within view of a 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 unless they are actually being used on the animal as part of the consultation.

f) POM-V, veterinary medicines containing psychotropic drugs or narcotics and all antimicrobial products must be stored behind the sales counter and must not be available for self selection.

g) Promotion of any human medicine for administration to an animal is restricted even if there is no equivalent veterinary medicine.

h) Wholesale dealers may send a price list of authorised human medicines to a veterarian for use under the cascade but only when specifically requested. The list must clearly state that the medicines do not have a Marketing Authorisation for veterinary use.

2.2 REQUIREMENTS FOR PROMOTION OF MEDICAL DEVICES

Specific requirements for promotion of medical devices are as follows:-

a) 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.

b) Medical devices classified as "Professional Use Only" should only be allowed to be promoted to health care proffessionals.

c) Medical devices meant for research use only should not be advertised or promoted to the general public.

d) Promotion to the public should not contain names and logos of any Health/ Science Authority and any of its professional groups or well known organisation that because of their influence could encourage the use of a medical device.

e) 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.

f) Promotion should not give any implication that the medical device can induce sexual virility or they are effective in treating sexual weakness or sexual excess and conditions such as premature ejaculation and erectile dysfunction.

g) Promotion should not contain any claim, statement or implication that the medical device is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure.

h) Promotion should not contain words, phrases, or illustrations which claim or imply the cure of any ailment, illness or disease other than from the relief of its symptoms E.g. complete cures, cure when other treatment fails, instant cure etc.

i) Promotion shall not expressly or implicitly claim, indicate or suggest that the medical device will prevent, alleviate or cure any of the following disease or conditions; Blindness; Cancer; Cataract; Drug addiction; Deafness; Diabetes Epilepsy or fits; Hypertension; Insanity; Kidney diseases; Leprosy; Menstrual disorders; Paralysis; Tuberculosis; Sexual functions; Infertility; Impotency; Frigidity; Conception and Pregnancy. Unless the

advertisement is distributed only to, or is contained in a publication intended for circulation to healthcare providers only or institution.

j) Promotion for Non-sterile Class A medical devices which are exempted from product registration should be done with care to ensure that presentations and advertisements for the intended use of a medical device must not deviate from their specifications. Some examples of acceptable claims for non-sterile Class A medical devices are shown in ***Annex I.***

k) Promotion of medical devices with supply restrictions must feature the restrictions on the advertisements. For example:-

- Contact lenses must be supplied via optometrists e.g. phrases like 'visit/consult your optometrist' should be featured.

- Medical devices intended for supervised supply by specified healthcare providers should feature advisories like 'Consult your pharmacist' as applicable.

l) Promotion to the general public should not directly or indirectly encourage indiscriminate, unnecessary or excessive use of the medical device.

m) Promotion should not exploit the ignorance and credulity of the public by including scientific data that the general public cannot verify or validate.

n) Promotion should not arouse fear in the minds of the public nor should they exploit the public's superstition.

o) 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.

p) Promotion to the public should not carry testimonials or recommendations by healthcare providers.

q) Testimonials featured in advertisements should reflect the typical experience of an average user of a medical device.

r) Testimonials based on fictitious characters should not been framed to give the impression that real people are involved.

s) Promotion claims of market prominence or uniqueness (e.g. 'No. 1'; '1st in the market') must be substantiated with independent third party research data.

2.3 REQUIREMENTS FOR PROMOTION OF COSMETICS

Requirements for promotion of cosmetics are provided in the Regulations 33 and 40 of the Tanzania Food, Drugs and Cosmetics (Control of Cosmetics) Regulations, 2010. Specific requirements for promotion of cosmetics are as follows:-

a) Promotion should not be presented as treating or preventing disease in human beings.

b) Promotional claims should take into consideration that cosmetic product typically have effects that are not permanent, and have to be used regularly to maintain their effects.

c) Promotion should not contain unacceptable claims commonly observed for some cosmetics as shown in the Table below:-

Product Type	**Unacceptable Claims**
Hair care products	• Eliminates dandruff permanently • Restores hair cells • Hair loss can be arrested or reversed • Stimulates hair growth
Depilatories	• Stops/retards/prevents hair growth
Nail products	• Reference to growth resulting from nourishment
Skin products	• Prevents, reduces or reverses the physiological changes and degeneration conditions brought about by agieng • Removes scars • Numbing effect • Prevents, heals, treats or stops acne • Treatment of cellulitis • Lose centimetres • Reduces/controls swelling/oedema • Removes/burns fat • Fungicidal action • Virucidal action
Oral or dental hygiene products	• Treatment or prevention of dental abscess, gumboils, inflammation, mouth ulcers, periodontitis, pyorrhoea, periodontal disease, stomatitis, thrush or any oral

d) Promotional claims can be softened or made less functional and more cosmetic 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 from 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 less oily".

3. MODES OF PROMOTION

Different methods are used to present a message to healthcare professionals and the general public for the purpose of promoting regulated products. The promotional methods that can be used are as follows:-

3.1 Still

Includes any promotional adverts in print media such as magazines, newspapers, journals, diaries, calenders, flyers, brochures, billboards, posters, branding on vehicles, buildings, benches and other print publications.

Information to be presented using this method should not be in a way that the reader has to turn the material around to read the text.

3.2 Sound

Includes any promotional adverts with sound effect such as broadcast over radio, radio cassettes or any audio.

3.3 Light and Sound

Includes any promotional adverts with light and sound effects, e.g. television, cinema advertisements and videos.

3.4 Web based

Includes any promotional adverts on websites. Promotion of prescription medicines are acceptable only on websites whose nature and content are directed to health care 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.

3.5 Sales Promotion

This is any activity with the purpose of introducing, publicising or promoting the sale of a product e.g. price-off, banded offers. It also includes giving discounts and banding of different pack sizes of the same product within the same range, with or without a discount distribution of samples. Such activities are allowed provided that they do not feature any product(s) more prominently than the rest.

3.6 Medical representatives and promotion personnel

a) Only medical representatives registered by the Pharmacy Council are allowed to carry out promotion of medicines and medical devices on behalf of manufacturers and distributors. The manufacturer and/or distributor will be responsible for the statements and activities of their medical representatives.

b) Medical representatives or any other persons involved in promotion of regulated products should have sufficient scientific knowledge about products they promote to enable them provide as precise and complete information as possible.

3.7 Promotional Samples

a) There should be no sale or supply of samples of medicines or medical devices to any member of the public for promotion purposes.

b) 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.

c) The free samples provided by medical representatives should be labelled "Physician Sample not for Sale".

d) There are no restrictions applicable to cosmetics with regard to provision of this section.

3.8 Promotional meetings

a) 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 the Authority.

b) Application procedures for a permit to conduct promotion meetings are as follows:-

(i) Applications should be made by filling in the application form as prescribed in ***Annex II*** and submitting to the Authority not less than 2 weeks before the meeting.

(ii) The application should be accompanied by prescribed fee and samples of all materials and products to be used in the meeting for promotional activities.

c) Companies shall organize or collaborate in events of a purely scientific-professional nature, are not permitted to organize or collaborate events containing elements or activities of an entertainment of recreational nature.

d) The contents of presentations at symposia or seminars shall be factual, accurate, without omission and not biased towards any particular company's products. Sales of medicines during the meetings are prohibited.

3.9 Promotion in public health programme/campaigns

a) 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.

b) Public health programme such as government controlled programme (vaccination & malaria campaigns etc) that have been approved by the responsible Ministry are required to obtain an approval letter from the Authority.

c) Advertisements to the general public should not contain material which refers to recommendations by scientists or healthcare professionals which could encourage consumption of products.

4. STAKEHOLDERS' RESPONSIBILITIES

In order to effectively excute its functions including management and control of product promotions, TFDA has to work in close cooperation and collaboration with all stakeholders. Stakeholders' involvement in all TFDA undertakings is of paramount importance for the Authority to attain its vision and mission of protecting and promoting public health.

The various roles and responsibilities of different TFDA stakeholders inline with promotion of regulated products are outlined hereunder:-

4.1 Dealers of regulated products

Dealers of medicines, medical devices and cosmetics include manufacturers, importers and distributors, suppliers, wholesalers and retailers. Generally, dealers are responsible to ensure that their products conform with quality, safety and efficacy standards and are officially authorised by TFDA to be marketed in Tanzania before subjecting them to promotions. Moreover, they have to obtain permits and licenses to legalize their operations and ensure that they refrain from illegal dealings and malpractices in relation to product promotional activities.

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. Moreover, the information provided must conform with TFDA's 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 TFDA in sharing information relating to quality, safety and efficacy of medicines, medical devices and cosmetics.

4.2 Local Government Authorities and Law enforcers

TFDA closely collaborate with Regional Administration and Local Goverment Authorities (RALGAs) and other law enforcers such as police and judges in enforcing the Tanzania Food, Drugs and Cosmetics Act Cap 219. In course of improving efficiency and access to TFDA services, some of TFDA functions have been delegated to Local Government Authorities through the Delegation of Powers and Functions Order of 2006, GN No. 162.

Therefore, the roles and responsibilities of law enforcers are to sensitize their employees to voluntarily enforce the TFDCA, Cap 219 and its Regulations including one for control of medicines, medical devices and cosmetics promotion in this case.

They have to work as law enforcers and hence are obligied to advocate voluntary compliance to existing laws, regulations and guidelines. Specifically, Law enforcers are responsible to:-

a) Enforce the requirements and directives of the laws, regulations and respective guidelines for medicines, medical devices and cosmetics promotions and the general essence of regulating product promotion.

b) Give correct and timely information about requirements of the existing laws and regulations in ensuring quality and safety of regulated products.

c) Sensitize and create awareness on the role of manufacturers, distributors and dealers of medicines, cosmetics and medical devices in relation to the enforcement of existing laws and voluntary compliance to these guidelines.

d) Timely handling stakeholders complaints/complements relating to promotion/advertisement of medicines, medical devices and cosmetics.

e) Report any contraventions and/or all defaulters of the laws especially dealers who deliberately give out exaggarated or misleading information about quality, safety and efficacy of medicines, medical devices and cosmetics.

f) Arrest defaulters and take them to the court of law.

g) Collaborate and cooperate with all TFDA stakeholders.

4.3 Health care professionals

Health care proffessionals are amongst 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 health care proffessionals are responsible to:-

a) Lawfully participate in product as well as health promotion campaigns to influence rational use and raise awareness of health issues and disease prevention.

b) Report to the Authority any contraventions and/or all defaulters of the laws especially dealers who deliberately give out exaggerated or misleading information about quality, safety and efficacy of medicines, medical devices and cosmetics.

4.4 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 as follows:-

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 TFDCA, Cap 219 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 exaggerated 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 official approval from TFDA.

e) To cooperate with TFDA in enforcing the laws by sharing information about public perception on the quality and safety of regulated products including their concerns/complaints on advertisements and promotions used.

f) To give constructive comments and recommendations on how to effectively and efficiently control product promotions.

4.5 General public

All promotions and advertisements prepared by dealers are made in a way to pursuade 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 TFDA on the quality safety and efficacy of medicines, medical devices and cosmetics.

b) Require TFDA to always provide updated information regarding 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.

d) Report to the Authority any contravention and/or defaulters of the laws especially dealers who deliberately give out exaggerated or misleading information about quality, safety and efficacy of medicines, medical devices and cosmetics.

e) Cooperate with TFDA in enforcing the laws by sharing information about individuals' perception on the quality safety and efficacy of regulated products including concerns/complaints on advertisements and promotions used.

f) Continously recommend on how product promotions and advertisements can be controlled effectively and efficiently to protect the general public.

5. 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 cosmetic that in his or 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 be made to the Authority in the prescribed form attached as ***Annex III***. The form can be obtained from TFDA headquarters and zone offices or through the TFDA website www.tfda.or.tz.

b) Complaint forms that have not been completed and signed will not be processed.

c) A submitted complaint should have details of when and where the promotion advert was seen and if possible a copy of the advertisement, together with details 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.

6. APPLICATION FOR APPROVAL OF PROMOTIONAL MATERIALS

a) Applications for approval of promotional materials for medicines, medical devices and cosmetics shall be made by submitting a dully filled application form attached as ***Annex IV*** accompanied with prescribed information as detailed in these guidelines.

b) Applications shall be accompanied by the following:-

- a non-refundable application fee;
- 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;
- 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: Documents such as video clips should be viewable via Windows Media Player compatible with Windows 7 version and thereafter.

c) Any application that will not be accompanied by appropriate fees will not be accepted.

d) The fees may be paid directly to TFDA or by bank transfer to:-

Tanzania Food and Drugs Authority,
Account No. 100380013 USD, Citibank, Tanzania Ltd.
Dar es Salaam - Head office Peugeot House, 36 Upanga Road,
P. O. Box 71625, Dar es Salaam Tanzania
Swift Code: CITITZTZ.

Local currency: Account No. 6503900110,
National Microfinance Bank, Kariakoo Branch
OR by banker's draft.

e) The approval for promotional material will be valid for 12 months. Advertisement that is still in use must be re-certified at intervals of no more than 12 months. Approval for promotions on specific events are excluded from this rule.

7. ANNEXES

Annex I:

TANZANIA FOOD AND DRUGS AUTHORITY

TFDA
Tanzania Food & Drugs Authority

ACCEPTABLE CLAIMS FOR NON-STERILE CLASS A MEDICAL DEVICES

S/No.	Examples of non-sterile Class A medical devices	Acceptable product claims
1.	Adhesive bandage / dressing / strip / tape	• cover and protect intact skin or wounds • approximate the skin edges of a wound • support an injured part of the body • fix dressings to skin • bind/attach/secure objects to the skin/body part • additional properties where substantiated e.g. waterproofing
2.	Adhesive tape remover	• remove adhesive tape and its residue from the skin or other surfaces
3.	Nasal aspirator, manual	• enable gentle suction and clearing of excessive mucus from the nasal passages to facilitate easier breathing
4.	Ice bag/collar	• provide dry cold therapy to a limited external surface area of the body • alleviate pain and/or promote healing in minor injuries of the body
5.	Bandage, self-adherent	• secure a dressing • maintain pressure over a compress • immobilise a limb or other body part
6.	Bandage, clavicle	• maintain fixation and longitudinal extension of the clavicle during a period of treatment
7.	Bandage, elastic	• provide support or local pressure to a part of the body, especially a joint, while allowing movement

S/No.	Examples of non-sterile Class A medical devices	Acceptable product claims
8.	Bandage, gauze	• cover and protect wounds
9.	Bandage, gauze, roller	• bandage heads, limbs, and difficult to dress wounds (e.g., burns, plastic surgery, or orthopaedic wounds)
10.	Bandage, traction	• assist in exerting desirable tensile (pulling) forces on the body
11.	Bedpan	• receptacle for urine and faeces
12.	Abdominal / ankle / breast / chest / sternum / wrist binder	• support relaxed abdominal walls/ ankle joint/ breasts/ribs and chest/sternum/ wrist joint
13.	Blanket, general purpose	• wrap or cover a person for warmth and comfort
14.	Bottle, heating / cooling	• filled with either hot or cold water or ice for the purpose of applying heat or cold therapy to an area of the body
15.	Contact lens case	• for the storage of contact lenses when the lenses are not being used
16.	Chair, bath / shower	• to be sat upon by a person who is either bathing, showering, or using some washing facility
17.	Chair, toilet	• allows an immobilised person/patient to utilise a standard stationary toilet without leaving the chair
18.	Compression dressing	• compress a local area, e.g., to stop bleeding, prevent oedema • provide support for varicose veins or ostomy aids
19.	Compression garment	• fit over and apply pressure to a specific body part(s) (e.g., thighs, hips, buttocks)

S/No.	Examples of non-sterile Class A medical devices	Acceptable product claims
		• may aid in the readjustment of overlying skin, after significant subcutaneous tissue removal (e.g., fat removal after liposuction)
20.	Cotton ball	• apply medications to or remove liquid from various parts of the body
21.	Cover, thermometer	• prevent cross-contamination between patients and/or environmental exposure
22.	Gloves, examination	• prevent contamination between patient and examiner
23.	Heat/ cold pack	• provide cold/hot therapy to body surface and/or underlying tissue, e.g. muscle
24.	*Mask, Face*	• prevent contamination to patient/ health care personnel
25.	Pressure alleviation pad	• prevent pressure sores, e.g. bed sores or decubitus ulcers occurring on the parts of the patient's body which are prone to this
26.	Finger protector	• protect an injured finger from further trauma during the healing process
27.	Protector, foot (e.g. *Bunion/ Callus/ Corn protectors, pads, plasters)*	• protect that part of the foot from friction against surfaces and knocks against objects • may have additional properties (e.g. waterproof, lubricating, hypoallergenic) where substantiated
28.	Patient restraint	• temporarily secure the arm or leg of an adult patient to prevent injury or hazards. when anchored to a fixture or furniture part (e.g., a bedrail) • restrict movement of the patient and prevent the patient from interfering with treatment
29.	Restraint, fingers	• restrict finger mobility and prevent potential

S/No.	Examples of non-sterile Class A medical devices	Acceptable product claims
		injury
30.	Restraint, body	• secure a patient's arms to the torso to prevent self-inflicted injury
32.	Orthotic shoe	• support, align, prevent, or correct deformities of the feet to help improve their function
33.	Cast boot	• boot-like cover for a foot enclosed in a leg cast
34.	Shoe, Cast	• protect the cast material and provide support
35.	Sling	• support and limit the range of motion of an injured limb during the healing period • support and limit the range of motion of a body in transport
36.	Splint	• immobilise an injured body or body part
37.	Splint, nasal, external	• immobilisation of parts of the nose typically after a fracture or treatment • may function as a truss-like support on the outside of the nose
38.	Cast stockinette	• used as padding under a cast or splint
39.	Stocking, stockinette	• hold bandages in place • place uniform pressure on a leg, finger, arm, or other part of an extremity • pad the area under a cast or splint • cover a stump when a prosthesis is worn
40.	Stocking, medical support	• support, correct, prevent deformity, or to align body structures for functional improvement
41.	Tourniquet strap	• compress the arteries and regulate the blood

S/No.	Examples of non-sterile Class A medical devices	Acceptable product claims
		flow
42.	Transfer aid, person	• assist in the physical transfer of a person/patient, e.g. ill, disabled or infirm, from one position to another
43.	Walking crutch / frame / table / stick	• assist a disabled or infirm user in walking by providing a means of support and increasing their ability to move around without attendance from another person
44.	Wheel Chair	• wheeled personal mobility device for a disabled user not having the full capacity to walk by him or herself

Annex II: Application form for permit to conduct promotion meetings

TANZANIA FOOD AND DRUGS AUTHORITY

TFDA
Tanzania Food & Drugs Authority

APPLICATION FOR PERMIT TO CONDUCT PROMOTION MEETING

(All information supplied in this form must be typed or written in block capital letters.)
The application fee must accompany the application

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 applicable).....

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)

Annex III: Complaints Form

TANZANIA FOOD AND DRUGS AUTHORITY

TFDA
Tanzania Food & Drugs Authority

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	
3.0 ADVERTISEMENT TYPE	
3.1 Magazine/Newspaper	
3.2 Radio	
3.3 Cinema	
3.4 Outdoor/billboard/shopping mall	
3.4 Television	
3.5 In/on public transport	
3.5 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 products unauthorized (Not registered) by the Authority	Yes: ..... No:.....
4.5 Advertising complaints related to prescription drugs	Yes: ..... No:.....
4.6 Contact details so that we may contact you for clarification and to advise you of the outcome of the case.	
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	
Signature of complainant:	**Date:** .....

Send this form to:

Director General
Tanzania Food & Drugs Authority (TFDA)
P. O. Box 77150, Off Mandela Road, Mabibo External,
Dar es Salaam
Email: info@tfda.or.tz

Or TFDA Zone Offices

Annex IV: Application form for approval of promotional materials

TANZANIA FOOD AND DRUGS AUTHORITY

TFDA
Tanzania Food & Drugs Authority

APPLICATION FORM FOR APPROVAL OF PROMOTIONAL MATERIALS

(All information supplied in this form must be either typed or written in block capital letters.)

Applicant Particulars

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

Sponsor particulars (if different from the applicant)

Name of Sponsor:..... .....
Address: .....
Contact person: ..... **Email**:.....
Telephone Number: ..... **Facsimile Number:** ....

Product particulars

Product category (please tick the appropriate box)
Human Medicine [ ] Veteinary Medicine [ ] Herbal Medicines [ ] Traditional Medicine [ ] Medical Device [ ] Cosmetic [ ]

Product Name(s) .....
Registration number.....
Name of registration holder.....
Type of Advertisement: .....
Type of material: (please tick the appropriate box)
Poster [ ] Leaflet [ ] Cinema [ ] Outdoor/Billboard [ ] In/On Public Transport[ ]
Magazines/Newspaper[ ] Literature [ ] 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 cassette.)
[ ] Current indications of use as indicated on Certificate of Registration (where applicable).
[ ] Copy of any research/surveys/data mentioned 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 application is true and correct.
Signed: .....
Date:.....

FOR OFFICIAL USE ONLY

Fees Tshs..... Receipt No..... of .....
Permit granted/not granted because.....
.....
.....
Permit No..... Approved by .....of .....

....
Date Director General