REPUBLIC OF KENYA

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

GUIDELINE FOR ADVERTISEMENT AND PROMOTION OF HEALTH PRODUCTS AND TECHNOLOGIES

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Date : 13/07/2022

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ABBREVIATIONS

SMPc	Summaries of Product Characteristics
PILs	Patient Information leaflets
PARs	Public Assessment Reports
PPB	Pharmacy and Poisons Board (PPB
HCPs	Health Care Professionals

GLOSSARY

“Applicant” means a person, organization, company, or entity seeking approval to advertise/promote a medicine or medical device.

“Act” means the Pharmacy and Poisons Board Act.

“Advertisement” includes a notice, circular, label wrapper, or another document, and an announcement made orally or by means of producing or transmitting light or sound designed to promote the supply, sale or consumption of health products.

“Board” means the Pharmacy and Poisons Board appointed under the provisions of section 3 of the Cap 244.

"**Claim**" means any presentation, that states, suggests, or implies that the product has particular qualities relating to its origin, nutritional properties, nature, processing, composition, or any other quality, and is capable of the objective substation.

‘‘Dispense’’ about a medicine poison, means supplying a medicine or poison by prescription duly given by a duly qualified medical practitioner, dentist or veterinary surgeon.

“General public” means a person other than a healthcare professional.

“General sale drug" means any drug whose use does not need the direction or prescription by a medical practitioner, dentist, or veterinary surgeon.

“Health products and technologies” means all devices, medicines, systems, and procedures intended at improving health.

“Health care professional” means any person who has obtained health professional qualifications and is licensed by the relevant regulatory body.

‘‘Herbal drug" means a finished medicinal product containing plant and its preparation presented with the therapeutic or prophylactic claim and includes all preparations containing a plant material in part or wholly.

“Human and veterinary use” means any medicament or curative or preventive substance, whether proprietary or in the form of a preparation used in both humans and animals.

“Label” means a display of written, printed, or graphic matter on a product, the immediate containers, wrappers or accompanying the product.

“Manufacture" means any process carried out in the course of making a product or medicinal substance 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.

"Medium'' means newspaper, magazine, medical/journal, television, radio, Internet, 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.

"Medical claim" includes any statement that conveys information about the state or the attributes of a product in respect of its therapeutic use 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 farm houses;

"Medical device" means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material, or other similar or related article: intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes(s) of:

a) Diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for an injury;
b) Investigation, replacement, modification, or support of the anatomy or a physiological process;
c) Supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical or diagnostic purposes through in vitro examination of specimens derived from the human body and
d) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological, or metabolic

means, but which may be assisted in its intended function by such means.

"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;
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.

"Misleading Information" means information that gives a wrong idea or impression.

"Marketing authorization holder" means an entity that holds the marketing approval for a product;

"Media enterprise" means an organization whose business involves the collection, processing, and dissemination of news or news articles, or in entertainment and education through the media;

"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 drug and herbal drugs.

"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 the issue of a permit.

"New Chemical Entity" Means an active ingredient, including its salts and/or esters, not yet approved by the Board for marketing in Kenya.

''Prescription only health Products'' means any products required to be dispensed only upon a prescription given by a medical practitioner, dentist or veterinary surgeon, or any other person approved by the Cabinet Secretary.

"Product" means a medicine, medical device, or herbal drug.

“Promotion” any informal and persuasive activities by a manufacturing pharmaceutical company or distributor of medicines, or a body appointed by them, which induces the prescription, supply, purchase, or sale of any medicines.

“Promotional material” means any representation concerning the attributes of a product conveyed by any means whatever to encourage the prescription, supply, purchase, sale, and or usage of product.

“Publication” means the act of making information, stories, or pictures available to people in any medium including books, newspapers, magazines or electronic media.

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PREFACE

Advertisement and promotion of health products and technologies remains important means of creating awareness and dissemination of information to the general public and healthcare professionals.

There has been an increase in the number of advertisements and promotions especially on internet and social media indeed, a welcome activity. However, the increase has also been associated with inaccurate and misleading information on a number of health products including supplements and medical devices.

This guideline has been developed to provide information on the current minimum requirements for authorization to advertise and ethically promote such products with a view of causing a prescription, sale, supply or awareness to the general public.

It stipulates, among other things, elements of promotional advertisement and restrictions therein, basic requirements, and the application procedures for obtaining approval to advertise and promote.

All stakeholders are encouraged to be conversant with the guidelines and implement them in their respective practice. They are also called upon to continuously send in their recommendations on the best practices around the world in regard to advertisement and promotions.

The success of this initiative depends on the active contribution and cooperation of every stakeholder. We trust that all of us shall strive to uphold the standards of practice in health products advertisements and promotions in Kenya.

Dr. F M. Siyoi

Chief Executive Office

1.0 INTRODUCTION

The Pharmacy and Poisons Board is committed to its mission to ensure that advertisements and promotions of health products in Kenya are done within the legal framework and that the messages sent to the public and healthcare professionals remain factual, evidence based and not misleading.

This guideline has been prepared to provide persons involved or wishing to be involved in health products advertisements and promotions to know, which category of health products can be advertised and the requirements to have them approved by the Board.

It recognizes the difference in the level of protection from misleading information to the general public and the healthcare professionals who are subject matter experts and who can exercise their professional judgment on information and content.

2.0 LEGAL FRAMEWORK RESPONSIBILITY OF IMPLEMENTATION

This guideline shall be used in conjunction with the Pharmacy and Poisons Act, Chapter 244 sections 36, 37, 38, 39, 40, Laws of Kenya in all aspects. It reflects the Pharmacy and Poisons Board's current thinking on the legal and ethical promotion of health products.

Subject to the provisions of this Act:

a) Applications for the advertisement of any health product shall be made to the Board in the prescribed form and shall be accompanied by the prescribed fee;
b) No person shall advertise any health product or technology except with the written permission of the Board;
c) No health product or technology shall be promoted or advertised through any media, including social media unless it is registered by the Board;

d) No person shall take any part in the publications of any advertisement or promotion referring to a drug, medicine, medical appliance, or similar article in terms which in the opinion of the Board are considered to be exaggerated and to bear little or no relation to the pharmacological properties and action of the ingredients or components thereof;

e) No person shall take any part in the publication of any advertisement referring to any drug, appliance, or article of any description in terms, which are calculated to lead to the use of such drugs, appliances, or articles for procuring the miscarriage of women.

The Board reserves the right to request compliance with any additional requirements or make amendments in keeping with the knowledge, which is current at the time.

3.0 SCOPE

This guideline applies to;

a) advertisement and promotion of registered or listed health products and technologies to healthcare professionals and the general public.

b) wholesalers, distributors, and logistics companies who may influence the demand for health products and technologies.

4.0 OBJECTIVE:

The objective of this guideline is to;

a) regularize all advertisements, promotional materials, and information on health products and technologies available in Kenya.

b) articulate ethical criteria for conducting promotional advertisements and how to comply with applicable legal, regulatory, and professional requirements.

5.0 ELEMENTS OF ADVERTISEMENT AND PROMOTION

What constitutes advertisement/promotion

Any activity undertaken in the manner provided hereunder shall constitute product advertisement or promotion:

a) any written, pictorial, visual, or other descriptive matter or verbal statement with or without a medical claim designed to promote the prescription, supply, sale, or consumption of medicinal products;
   i. appearing in any paper, newspaper, diary, calendar, business cards, or any other print publication;
   ii. appearing on any television, cinema, radio, social media; or
   iii. circulated via electronic mail (e-mail) or short message service (SMS) or multimedia message (MMS);
   iv. distributed to the members of the public as branded items or
   v. press releases or product launches on new chemical entities;
   vi. telephone helplines and or point of sale materials;
   vii. brought to the notice of the members of the general public in any manner whatsoever; to promote the sale, prescription, supply, and consumption of the product;
   viii. branding on vehicles, buildings, benches, and other similar medium;
   ix. road shows and other similar means and
   x. any other means that may be considered by the Board as an advertisement.

b) the activities of medical representatives including detail aids and other printed material used by representatives to update healthcare professionals to promote purchase.

c) promotional materials to be used in sponsored meetings or workshops.

d) the provision of medical information with product claims to the general public

e) all other sales promotion of medical products and technologies 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.

What does not constitute advertisement/promotion

Unless the context states, the following activities that are not designed to promote sale and consumption of the product, shall not form health product advertisement and promotion;

a) factual, accurate, informative announcements and reference material concerning licensed medicines provided no product claims are made to healthcare professionals;
b) replies made in response to individual inquiries from healthcare professionals or employees in response to specific communications;
c) non-promotional information about pharmacy, prescription only, and other legal categories to the general public, press conferences, press announcements, television, radio reports and public relations activities;
d) summaries of product characteristics (SPCs), patient information leaflets, (PILs), public assessment reports (PARs), and direct responses to questions;
e) the mandated and registered packaging and pack information including the patient/prescriber information leaflet;
f) statements relating to human health or diseases provided that there is no reference to a specific product;
g) notification on pricing, bonuses, and incentives.

6.0 GENERAL REQUIREMENTS

a) The content of promotional materials must be detailed, balanced, accurate, informative, up to date, in good faith, and consistent with information approved during registration of the product.
b) Promotion of off-label and or unregistered indication is prohibited.
c) Promotional material sent under the guise of personal communications is inappropriate and unacceptable.

d) Clinical trials or safety studies should not be undertaken solely for purposes of promotion or advertisement.

e) Under co-promotion arrangements whereby companies jointly or individually promote the health product, each company should certify the promotional material or activity, as they shall be held jointly held responsible under the regulation.

f) The language should be simple to understand and or should not bring fear or distress to individuals or communities.

g) Advertisements should not contain any statements or visual presentations, which might lead to or support acts of violence, or criminal or illegal activity or appear to condone such acts or activities.

h) It should not contain statements or visual presentations, which are or are likely to be interpreted to be contrary or offensive to the standard of morality or decency prevailing in Kenya or in any way defamatory or humiliating to any segment of the public.

i) It should not contain pictures of sexual organs or any other indecent unacceptable images to the general public. Pictures other than those prohibited may be used on adverts but they must be aesthetic, not objectionable, and consistent with Kenyan culture.

j) It shall not contain misleading or unverifiable statements or omissions regarding quality, safety, and efficacy or value, which is likely to induce medically unjustifiable product use or to give rise to undue risks, such as:

k) It should not induce unwarranted anxiety among consumers about their condition by suggesting that the condition is of greater severity than is the case;

l) It should not suggest that the condition shall deteriorate if the consumer does not use the product or brand featured;

m) It 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 medicine or that health could be affected by not taking the medicinal product.

n) The content and labelling shall be in the trade name; generic name (INN) must appear immediately, below or adjacent to the most prominent display of the trade name.

7.1 SPECIFIC REQUIREMENTS

Advertisement to the general public

a) General sales shall be advertised to the general public only.

b) Pharmacy only health products may be advertised to the general public only within the confines of the pharmacy on materials such as point-of-sale, dummy boxes and others.

c) Controlled, narcotic and psychotropic substances are prohibited for the advertisement to the general public.

d) Price lists for pharmacy and prescription-only health products shall be advertised to the general public provided no indications/claims are made.

e) Exempted from this provision is the advertisement or promotion of a licensed vaccine approved by the Board or granted emergency use authorization granted by the Board, as part of a national government-controlled vaccination campaign or other licensed medicines or health technologies used in certain public health emergencies including in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation.

Promotion to the healthcare practitioners

a) General sales, pharmacy only, prescription only medicines, and medical devices shall be promoted to healthcare professionals qualified to prescribe, dispense, handle or supply.

b) Promotion of the following classes of antimicrobials to the HCPs on branded items that are otherwise easily visible to the general public such as lab coats, dust coats, umbrellas, etc are prohibited;

i. antibiotics
ii. antiparasitic
iii. antifungals
iv. antimalarials
v. antivirals
vi. antimycotics

c) The wording and illustrations shall be detailed, technical, and fully consistent with the latest scientific data.
d) The product name in the body of the text shall be described by its INN name only or INN with brand/trade name enclosed in the bracket.
e) Dissemination of the latest scientific or clinical information to healthcare professionals shall be carried out by as authorized by the Board.

Promotion and advertisement of medical devices

a) Medical devices that are categorized as general sales and do not require prescription or professional intervention shall be advertised to the general public.
b) Prescription-only medical devices and in-vitro diagnostics shall be promoted to healthcare professionals.
c) Medical device for research uses only shall not be advertised to the general public.
d) It should not suggest that the medical device can prevent or reverse the physiological changes and degenerative conditions brought about or associated with aging.
e) Medical devices with supply restrictions must feature the restrictions on the advertisements.
f) Marketing materials should not suggest that the medical device shall prevent, alleviate, or cure.
g) It should not imply that the medical device can induce sexual performance or is effective in treating sexual weakness or excess

and conditions such as premature ejaculation and erectile dysfunction.

Herbal and complementary medicine

a) It shall be promoted or advertised after listing or registration.
b) Indications shall be based on evidence of traditional use of a substance or product, and/or on scientific evidence.
c) Indications/claims shall be categorized depending on the level of a claim being made.
d) All indications must be true, valid, and not misleading, and should not lead to unsafe or inappropriate use of the product.
e) Evidence must relate to the whole product or the same active ingredient(s) with a similar dosage regimen, dose form and route of administration of the product, which the claim is being made.
f) Evidence must be available before claiming an intended use or indication for a product.
g) Advertisement of herbal products shall not imitate the general layout, text, slogan or visual presentation of another herbal medicine or conventional product in a way likely to mislead or confuse the consumer.
h) Such advertisement shall not be framed in such a manner as to exploit and promote any superstitions or be calculated to induce fear among consumers, causing them to purchase the herbal medicine and related product being advertised.
i) All advertisements shall strictly be in line with claimed indications as registered or listed by the Board.
j) Cautionary labels or disclaimer statements must be displayed on the label of advertisement materials for herbal medicine and related products.
k) It shall not contain such words as "magic" "miracle" or an exotic description such as "supper potency" or such other words as to induce the daily or continuous use of the product.

l) Any statement claiming or implying a superlative function such as "most effective" "least toxic, "best tolerated" or another special status such as “herbal medicine or related products’ of choice” shall not be used.

m) The use of terms clinically proven or effective is not permitted since registration of products is based exclusively on long-standing use.

n) Efficacy claims are not allowed for serious medical diseases and disorders.

o) Advertising which states or implies that a product is “safe” is unacceptable.

p) Advertising should not suggest that a product does not have any side-effect or that its safety or efficacy is because it is natural, nor should it include any description or detailed representation of a case history that may lead to erroneous self-diagnosis.

Vitamins

a) No advertisement should state or imply that good health is likely to be jeopardized solely because there is lack of dietary supplementation with vitamins.

b) Vitamins should not be advertised in any manner that they are a substitute for a balanced diet.

Weight management

a) Claims for weight management including weight loss, measurement reduction, clothing size loss, and weight control/maintenance, can only be made in conjunction with sensible lifestyle factors including a diet exercise.

b) References to support claims of slimming, fat burning, fat, and starch blocking should be linked using an asterisk to a clear disclaimer stating “this product has not been proven to burn fat or block starch”.

8.0 ADVERTISEMENT TO SPECIAL POPULATIONS

Pregnant and lactating women

a) Advertisements shall not suggest or recommend any medicinal products, except some vitamin and mineral supplements, for use by pregnant or lactating women.

b) Advertisements for self-care products shall not cause harm, or risk or convey a message that it is routine practice for pregnant women to medicinal products and that the unborn baby's development shall be affected if these products were not taken.

c) Where there is a suggestion for use of a product during pregnancy, all advertisements must encourage a cautious approach before use and include a statement that women should consult their healthcare professional before use.

Children and minors

a) It shall not be aimed principally or exclusively at children (under the age of twelve years).

b) It shall not show children using, or within reach of, health products without adult supervision.

c) Images of children used in promotions or advertisements shall not be used alone, rather, these shall be accompanied by adult images.

9.0 CONTENT FOR PROMOTIONAL ADVERTISEMENT

a) It shall contain the generic name, brand, or trade name and the name(s) of the active ingredient(s) using International Non-Proprietary Names (INN).

b) Approved indication(s), strength, dosage regimen and maximum allowed daily dosage in cases of herbal and complementary medicines.

c) Phrase "Maumivu yakizidi pata ushauri wa Daktari" or "if symptoms persist seek medical advice" or a similar meaning phrase in case of advertisements to the general public.

d) Reference to the current scientific literature as appropriate.

e) A disclaimer on any major side effects, adverse reactions, or warnings.

f) PPB approval reference number and contact details of the Marketing Authorisation Holder on every print media.

10.0 ETHICAL ADVERTISEMENT

a) There shall be no personal enrichment of healthcare professionals or other healthcare providers.

b) No gift, benefit in kind, rebate, discount, kickback, or any other pecuniary advantage shall be offered or given to members of the health professions, administrative staff, government officials, or the general public as an inducement to prescribe, lease, loan, supply, stock, dispense, administer or buy any healthcare product.

c) When in conflict with product posology, bonus offers, free samples, including competitions, and discounts offered directly to the general public are not permissible.

d) Healthcare professionals shall not ask for or accept any material rewards from companies, organizations, or individuals that sell or market health products. Sponsorship of healthcare professionals to attend seminars and the like, should not be used to influence them to promote specific health products.

e) Advertising to the general public shall 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. Material that refers in improper, alarming, or misleading terms to claims of recovery must not be included. This does not prevent a category claim such as “works faster than standard tablets,” provided it is supported by evidence.

f) Advertising to the HCP shall not claim that a product is the “best“ treatment for a particular condition since it cannot be substantiated as there are too many variables to enable such a sweeping claim to be proven.

g) Promotion shall not be disguised. Clinical assessments, post-marketing surveillance, experience programs and post-authorization studies shall not be disguised as promotion or advertisement. Such assessments, programs and studies shall be conducted with a primarily scientific or educational purpose.

h) Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which are sponsored by a company or distributor/importer should indicate by whom it has been sponsored.

11.0 FREE SAMPLES TO HCPs

a) The supply of free medical samples of licensed health products shall be made by an authorized medical representative to a dully qualified and registered healthcare professional qualified to prescribe for the purpose of acquiring knowledge and experience in dealing with the product.

b) Such qualified person shall be supplied with free medical samples on the following conditions:

   i. a limited number only of samples of each product may be supplied in any one year to any one recipient, and this shall be upon their acceptance e.g., for prescription only products, up to eight (8) packs for the first three (3) months post product launch, and up to 10 packs per year for all non-launch products.

   ii. they shall be not larger than the smallest presentation available for sale in Kenya.

   iii. they must be appropriately labelled and permanently marked "physician's sample – not for resale" (or similar).

   iv. Every sample shall be accompanied by a copy of the SPC with PIL/PI.

   v. All medical representatives shall provide quarterly reconciliation / report to the Board of samples issued with details of recipients and other product details.

c) Free medical samples shall only be provided upon a documented request by a healthcare professional or any other organization, as may be authorised to handle the respective product.

d) There shall be no solicited requests by the medical representatives to healthcare professional.

e) When samples are requested by healthcare professionals, they shall be given directly to the healthcare professional. No samples shall be given directly to the non-professionals unless otherwise expressively authorized in writing by the board.

f) Medical representatives and recipients shall maintain an adequate system of control and accountability of all product samples and shall be made accessible to the Board for inspection.

g) The superintendent pharmacist shall be responsible for maintaining control and accountability of all samples for controlled substances submitted for purposes of bidding for tenders and listing into the hospital formulary.

h) Samples shall be kept at all times under recommended storage conditions as detailed on the pack. In case of products that need refrigeration, they shall be provided to HCPs or clinics and refrigeration be assured upon arrival.

i) No samples for Narcotic and Psychotropic or controlled substances shall be handled and supplied by medical representatives.

12.0 ONLINE ADVERTISEMENT AND PROMOTIONS

The internet is used widely to provide information and to promote or advertise products and services. For Institutions or companies wishing to promote or advertise health products, medical devices or services through the websites/ or portals they shall conform to the following requirements;

General requirements

The fundamental requirements for promoting advertisement through social media platforms such as blogs, YouTube, WhatsApp, Instagram, Facebook

and Twitter are the same as for any other media and as such accuracy and fair balance shall always be upheld.

a) Advertisements shall be limited to general sales only.
b) The online platform shall be operated, maintained and supervised by a registered pharmacist or enrolled pharmaceutical technologist
c) The content of the e-commerce platform must not contravene the guideline, rules and the Act of Parliament.
d) Advertisement using social media accounts belonging to government agencies, professional associations, celebrities and social media influencers are prohibited.
e) Companies shall be required to have mechanisms of responding to "misinformation" posted by users on webpages or platforms owned, operated or influenced by the company (includes potential off-label information and false, misleading or biased materials) as well as controlling employees' comments and responses.
f) Companies and individuals shall be held accountable by the Board for any health product information posted on their webpages / portals owned, operated or influenced by the company.
g) Information, education awareness and campaign materials on healthcare products shall be reviewed and approved by the Board before being uploaded to websites and portals.

Licensed online pharmacies

a) Online website providing dispensing services aimed specifically at patients who already have a prescription, provided no product claims are made shall only list POM products and dispensing prices in a different page other than the landing page.
b) The landing page of the online pharmacy shall only list and advertise general sale health products with or without indicative prices.
c) Promotion of POM products on pharmacy website landing page is prohibited however factual, accurate and scientific information can be shared or posted.

d) Images of POM products shall not be displayed on any page, however trade names, summary of product characteristics and indicative prices shall be displayed.

Company websites and portals

Companies wishing to promote or advertise health products and services that may led to supply of general and prescription only health products, shall have two windows, one for healthcare practitioners whose access shall be restricted and another for the general public.

Window for the general public

a) The general public platform shall be used to advertise or provide information on general sales of health products and medical devices.
b) The home or landing page shall focus on general sales of health products and the services the website or the platform provides and shall not include any reference to named POMs, including price information. Links and navigation aids may be given for particular services including device demonstration but not to specific POMs.
c) Text and any small print or advertisements at the bottom of the home page shall not refer to specific POMs. This provision is designed to ensure that casual browsers are not presented with advertising for specific POMs.
d) Other pages about the health products, which the consumer chooses to access, shall contain non-promotional information provided this is presented in the context of accurate, factual and scientific.
e) Prices on the homepage, only indicative prices for a general sales product may be provided, any mention of prescription only medicines on the home page are likely to be considered as advertising of prescription only medicines to the public.
f) A factual list of prices for POM products may be provided on pages other than the home page. The price list should not include product claims or actively encourage viewers to choose a product based on the price.

g) Special offers on prices of health products should not be highlighted on the website as they are likely to promote irrational use. Free offers of health products offered during advertisements competitions or bonanzas are prohibited.

Window for healthcare professionals

a) The window for healthcare professionals shall have restricted access and shall be conspicuously labelled 'for healthcare professionals only'.
b) The content meant for information and education and awareness shall be technical, factual, current and consistent with the latest scientific literature.
c) Pharmacy and POM products shall be listed in this window and shall be accompanied by limited information as contained in the Patient Information Leaflet or SPCs.
d) There shall be a declaration that the listed health products or technology can only be obtained under a valid prescription from a registered medical practitioner and self-prescribing is not recommended on each window or section of the document viewed.
e) A journal which is published or posted on the internet and which is expressly stated to be for healthcare professionals is considered to be directed at persons qualified to prescribe or supply medicines and the promotions contained within the journal should be restricted and comply with the law.

13.0 PRESS RELEASES AND PRODUCT LAUNCHES

a) Press releases for new chemical entities and health technology innovations are allowed only once and shall be fully factual and non-promotional.
b) The use of brand names shall be accompanied by INN names.
c) When responding to enquiries from the public about prescription only medicines, companies should ensure that such responses are

rational, non-promotional and limited to the subject matter of the enquiry.

14.0 PROMOTIONAL MEETINGS

a) No unregistered health product shall be displayed or circulated as promotional material whether at the national or international meeting.

b) All promotional materials to be used in any meetings or gatherings must be approved by the Board prior to use.

c) The Board shall be notified of any such meetings, workshops, conferences, seminars, symposia, webinars, awareness campaigns, or exhibitions organized or sponsored by any company where a health product or health technology may be promoted to the healthcare professionals at venues other than the healthcare facilities.

d) The notification shall exclude product promotional meetings held by medical representatives to healthcare professionals at the healthcare facilities.

e) Any person/company/organization wishing to conduct such meetings shall provide a summary of the meeting detailing;

   i. Type and title
   ii. Date and venue
   iii. Target audience and approximate number of participants
   iv. Brief description and the expected outcome(s)
   v. List and approval reference numbers of promotional materials to be used
   vi. Name and address of the convener and sponsor
   vii. Links (online) meetings.

f) The contents of presentation in those meetings shall be factual, accurate, without omission, and not biased towards any particular company's products.

g) Sale of health products or issue of free medical samples during such meetings or trade shows where drugs are exhibited is prohibited.

h) Companies shall organize or collaborate in conducting events of a purely scientific and professional nature in clinical, educational, conference or other settings, including hotel or other commercially available meeting facilities conducive to the effective transmission of knowledge but not in entertainment or recreational places.

i) Companies may not provide or pay for any stand-alone entertainment or any recreational event or activity for any HCP.

j) Companies shall not pay HCPs for their time whilst attending the CPD events under the guise that such events are scientific meetings or advisory board meetings.

k) Applications shall be made by logging in into the PPB portal or manually in case of products that have not been uploaded into the portal.

15.0 STAKEHOLDER RESPONSIBILITIES

Marketing Authorization Holders (MAH)

They shall;

a) Be responsible in ensuring that their products are registered or retained by the Board and that they conform to the quality, safety and efficacy standards before they subject them to promotions and advertisements.

b) Provide product education and training to HCPs in the interest of ensuring the appropriate, safe and effective utilisation of a particular type of medical technology.

c) Ensure that its medical representative's and marketing team refrain from illegal and an authorized practices in relation to product promotional activities.

d) Ensure that the information provided about their respective products are correct and in accordance with this guideline, rules and the Act of parliament.

e) Ensure compliance with the following requirements if they are involved in any patient support program: -

i. no incentives, other than material that shall enhance positive health outcomes and compliance, are provided to patients to become involved in these programs;

ii. the data collected from these programs shall not be used for any purpose other than to increase positive health outcomes and never for promotional activities and

iii. the duration of these programs is appropriate to the disease state treated by the product involved;

iv. report any contraventions of the laws and regulations and be ready to collaborate and cooperate in sharing information.

Healthcare professionals

They shall;

a) Lawfully participate in product as well as health awareness campaigns to market, educate and share information to influence rational use and raise awareness of health issues related diseases, prevention, treatment and alleviation.

b) Report to the Board any contraventions especially misleading, inaccurate and exaggerated information about quality, safety and efficacy of health products and technologies.

Media enterprises

They shall;

a) Only advertise approved promotional materials by the Board.

b) Shall comply with the requirements of this guideline, rules and the Act of Parliament.

c) In partnership with the Board promote rational use of health products and technologies.

Communication Authority of Kenya (CAK)

They shall;

a) Collaborate with the Board in Monitoring the activities of e-commerce licensed entities promoting advertisements and marketing of health products.
b) Enforce compliance with the licence terms and conditions as well as the law for e-commerce entities contravening Cap 244 governing promotion and advertisements of health products.

General Public

They shall;

a) Request product related information from the Board on the quality, safety, efficacy, registration or listing.
b) Report and share any information with the Board related to advertisement or promotion that they suspect to be false, misleading or contravenes the law and the regulation.
c) Participate in the review process of the relevant documents related to advertisements and promotions.
d) Collaborate with the Board in promoting rational use of health products.

16.0 CLAIMS, REFERENCES AND COMPARISONS

Claims;

a) All claims, descriptions, and comparisons which relate to matters of objectively ascertainable facts should be capable of substantiation.
b) Advertisements containing statistical claims should be supported by the latest scientific data.
c) Claims pertaining to product safety should not imply, whether directly or indirectly that the product is not associated with or free from any side effects. Phrases such as “No side effects,” “No harmful effects,” “and no toxic or adverse effects” are disallowed.

d) Products containing natural ingredients should not suggest that the safety or efficacy of the product is due to the fact that it is natural.

e) Whilst it is acceptable to make flavour claims, advertising shall not emphasize the sensory aspects of a medicinal product, such as a flavour or cosmetic attributes to the extent that consumers may believe that the product is a food, cosmetic or other non-medicinal product.

f) All claims should be capable of substantiation either by reference to approved labelling or by latest scientific evidence not more than 5 years. Such evidence should be readily available and reproduced upon demand.

g) Claims of effectiveness relating to speed of action, absorption, dissolution, distribution or other pharmacokinetic particulars are only acceptable if substantiated by evidence or is indicated in the approved label.

h) For origin claims, there should not be over-emphasis to highlight the manufacturer or foreign country of origin in promoting the efficacy of a product.

i) For 'Before' and 'After' claims, advertisements should not contain improper, exaggerated or misleading claims or visuals to represent changes in the human body and should not depict a more serious or chronic condition.

References;

a) Research results and data as well as reference to or quotes from technical and scientific literature should be of a standard recognised by scientific journals.

b) Statistics should not be presented to imply that they have a greater validity than is the case.

c) Scientific term(s) or jargon that is irrelevant should not be used to make claims that appear to have a scientific basis which they do not possess.

Comparisons;

a) Comparisons shall be substantiated and must not be left up to interpretation; hanging comparisons must not be made, whereby a health product is described as being better or stronger without stating against which criteria the health product is compared to.

b) Graphs, tables and pictorial representations should only be included if they are relevant to the claims or comparisons being made. They must not mislead with the use of incomplete, incorrect unusual scales or suppressed zeros.

c) A graph, table or pictorial can be adapted provided it is clear and its true meaning is not distorted. If a graph has been adapted from a paper, it must be stated so.

d) If an original table is not produced in its entirety, the adaptations shall not mislead and must be clearly demonstrated.

e) Price comparisons must be accurate, fair and must not mislead. A valid comparison may only be made where a price comparison is made on the basis of the therapeutically equivalent dosage requirement for the same indication.

17.0 PRODUCT ENDORSEMENTS AND RECOMMENDATIONS

a) Advertisements to the general public can contain materials, which refers to recommendations by scientists, health professionals, health professionals' bodies, provided that there is evidence that this is the case and that it does not contravene the product's package insert and condition/s of registration.

b) Recommendations by celebrities, influencers or well-known organizations who, because of their celebrity status, could encourage consumption of the health products is prohibited.

c) Use of healthcare workers or persons purporting to be healthcare workers in promoting medicines is prohibited.

d) Advertisements should not suggest that their product is "special" or different from or better than other medicines because it has been granted a marketing authorization or registration. Nor should an

advertisement state that a product has PPB/WHO or any other similar approval.

18.0 PROHIBITED ADVERTISEMENTS AND PROMOTIONS

No person shall take part in the publication of an advertisement referring to a drug, appliance or article of any description in terms, which are calculated to imply that such drugs, appliances or articles may be effective for;

i. The cure of syphilis, gonorrhoea or soft chancre in any of their forms
ii. The prevention, relief or cure of Bright's disease, schistosomiasis, cancer, tuberculosis, leprosy, lupus, diabetes, epilepsy or fits, locomotor ataxia, paralysis, or infantile paralysis.
iii. The cure of arterio-sclerosis, septicaemia, diphtheria, dropsy, erysipelas, gallstones, kidney stones, and bladder stones, goitre, heart disease, tetanus or lockjaw, pleurisy, pneumonia, scarlet-fever, smallpox, trachoma, amenorrhoea, hernia or rupture, blindness, or any structural or organic ailment of the auditory system.
iv. The cure of any habit associated with sexual indulgence, or of any ailment associated with those habits; or the restoration or stimulation of the sexual functions.

19.0 APPLICATIONS AND REVIEW PROCESS

a) All applications shall be made through the Pharmacy and Poisons Board Portal. In case of manual applications, it shall be made to the Chief Executive Officer, Pharmacy and Poison Board as per the prescribed application form in **Annex II.**
b) Any application uploaded into the portal without payment within 30 days shall be removed.
c) All application, fees shall be charged
d) per product per media and payment shall be made through mobile money, cheques or bank transfer to the Pharmacy and Poisons Board accounts.

e) Once the application has been accepted and evaluation fees paid, review of the application by reviewers shall take a maximum of 30 working days.

f) Applications shall be classified as low or high risk. All branded materials shall be classified as low risk whereas non-branded materials shall be classified as high risk.

Online applications

The following documents shall be uploaded in the advertisement portal.

a) TV advertisement; detailed storyboard of the proposed advertisement and scripts of the messages.

b) Radio advertisement; detailed script.

c) Print media; final proposed advertisement/scripts.

d) Branded items; image of the final branded item and submission of three samples of the branded items to the Board.

Manual Applications

The following documents shall be submitted in case of manual application

a) One CD copy of the final advertisement.

b) Three copies of script for TV, radio or social media advertisement.

c) Three copies of final samples/artwork.

d) Three samples of the branded items.

Screening checklist

a) Proof of registration of the company that wishes to advertise with the PPB;

b) Proof of registration or retention of the product to be advertised with the PPB;

c) Payment of the of Kshs. 5000 per proposed advertisement, per medium, per product;

d) Copy of updated 'annual practice license' of the superintending Pharmacist / Pharmacist in charge of the company;

e) List of active ingredients (contents) of the health product in INN;
f) List of current scientific references;
g) Current physical address of the MAH printed on the sample material except for branded items.

Appeals

a) Any person aggrieved by a decision of the Board in relation to any application shall make representations in writing to the Chief Executive Officer.
b) If after consideration of the representations, the Board is satisfied it may approve the application and if not satisfied it shall reject the application.
c) An appeal shall be lodged within thirty (30) working days.

Validity

a) All approved advertisements and promotions shall be valid for one year from the date of approval.
b) An approval reference number shall be quoted for each promotional material. The applicant is required to quote this reference number whenever any correspondence is made regarding that advertisement or promotion.
c) It shall be the responsibility of the Marketing Authorisation Holder to either withdraw all advertisement and promotional materials from the last point of distribution upon expiry of the stated validity or reapply to the Board for renewal.

20.0 OFFENCES, PENALTIES AND ENFORCEMENT

Offences and penalties

Any person who contravenes the provisions of this guidelines shall be subject to the;

a) Legal actions as per the Act of Parliament Cap 244;
b) Regulatory actions;
c) Disciplinary actions.

Enforcement

Compliance to this guideline, the rules and the Act of Parliament shall be enforced by the staff from the Departments of Product Safety, Inspectorate and Enforcement, Medicines Evaluation and Registration and Pharmacy Practice.

21.0 COMPLAINTS AND FEEDBACK

a) All complaints shall be addressed to the Chief Executive Officer, Pharmacy and Poisons Board.

b) The Board shall investigate all complaints received from anyone who in his or her view is misleading or otherwise fails to comply with the legal requirements.

c) All complaints shall be made to the Board in the prescribed form in **Annex III.** The form can be obtained from PPB headquarters and regional offices or through the PPB website www.pharmacyboardkenya.org.

d) Complaints shall have details of when and where the advertisement was seen, if possible, a copy of the advertisement, together with details of the concerns about the advertisement.

e) The PPB is particularly keen to receive complaints where the advertisement may have an adverse impact on public health.

f) Investigation into the complaint shall be done within thirty (30) working days and should the investigation take longer, the complainant shall be updated.

g) The Board shall share with the complainant the outcome of the case.

22.0 REVIEW OF THE GUIDELINES

a) This guideline shall be reviewed regularly after every three (3) years or as required based on feedback received from the stakeholders and the changing pharmaceutical industry and the regulations.

b) We encourage the stakeholders to continuously send in their recommendations on this guideline so as to make it relevant to the

current practices around the world in as far as health products and technologies advertisement and promotions are concerned.

23.0 REFERENCES

1.0 Guidelines to the South African code of practice for the marketing of health products.

2.0 Guidelines on advertising & promotion of medicines; Pharmaceutical Regulatory Authority Zambia first edition April, 2008.

3.0 Guideline for control of promotion and advertisement of medicines, medical devices and cosmetics in Tanzania.

4.0 Advertising of medicines: Guidance for providers offering medicinal treatment services Medicines and Healthcare products Regulatory Agency (MHRA)

24.0 REVISION HISTORY

Pharmacy and Poisons Board	**Revision History**			**HPT/PDS/GUD/046**
Rev No. 2	**Date**	**Prepared By: MIO**	**Sections Revised**	**Description of change**
Rev No. 2	13/07/2022	MIO	7.3	Introduced classes of antimicrobials not to be promoted to HCP on branded items
Rev No. 2	13/07/2022	MIO	9.0	Added inclusion of approval reference number
Rev No. 2	13/07/2022	MIO	11	Amended to include conditions and accountability of free samples
Rev No. 2	13/07/2022	MIO	14	Amended to include requirement of notification of meetings to the Board

25.0 CONTRIBUTOR'S

1. Dr. Fred Moin Siyoi- CEO, Pharmacy and Poisons Board
2. Dr. Ahmed Mohamed- Director, Health Products and Technologies,
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4. Dr. Jacinta Wasike- Director, Corporate Affairs, PPB
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7. Dr. Nancy Cherotich-Medicines Information, PPB
8. Dr. Christabel Khaemba- Pharmacovigilance and PMS, PPB
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13. Dr. Lydia Tuitai- Clinical Trials Registration and Inspection, PPB
14. Dr. Tom Mwangi Kauki- Enforcement and Surveillance, PPB
15. Dr. Sichei Cheworei – Quality Control Department, PPB
16. Dr. Allan Kyalo- Trade Affairs
17. Mr. George Muthuri- Training and CPD, PPB
18. Mr. Gedion Murimi- ICT, PPB
19. Ms. Miriam Achieng'-Products Safety,
20. Kenya Association of Pharmaceutical Industries

14.0 ANNEXES

Annex 1: Application form for approval to conduct promotion meetings

PHARMACY AND POISONS BOARD

Form for conducting promotional meetings

1	**Applicant Information**	
	Name of applicant	
	Registration/enrol number	
	Cadre	
	Telephone	
2	**Type of promotional meetings**	
	Workshops	
	Conference	
	Product Launch	
	Exhibitions	
	Symposia	
	Advisory Board meetings	
	Webinars	
	Others	
3	**Company/ Sponsor Information**	
	Name of company/sponsor:	
	Contact person	
	Telephone	
	Email	
	Location	
4	**Products promoted** (attach list of products and approval letters)	

	Name of Product	**Material description**	**Validity date**
5	**Summary of the meeting**		
	Title		
	Date	**Start Date:** **End date**	
	Name of the venue		
	Location		
	Brief description		
	Target audience		
	Expected outcomes		

Annex 1I: Application form for approval of promotion materials

PHARMACY AND POISONS BOARD

Form for approval of advertisement/promotional materials

1	**Company Details**			
	Name of company			
	Registration No			
	Location			
2	**Applicant Information**			
	Name of applicant			
	Registration/enrol number			
	Cadre			
	Telephone			
	Email address			
3	**Product Particulars**			
	Name of Product	**Strength**	**Reg No**	**Type of Media**
4	**Application check list**			
	A copy of the proposed advert			
	Proof of payment			
	Copy of reference materials			
	Copy of previous approval			
5	**Applicant Declaration**			

	.....declare that the information contained within this application is true and correct.	**Date .....** **Sign.....** **Stamp.....**

6	**FOR OFFICIAL USE ONLY**		
	Name of Product and Strength	**Approved**	**Rejected**
	Reason for rejection		
	Name of officer		
	Sign:		
	Date:		

Annex III: Complaint Form

PHARMACY AND POISONS BOARD

1.0	**Complainant/ Reporter details (optional)**		
	Name of the person/company/organization		
	Email		
	Telephone		
2.0	**Product Details**		
	Name of Product	**Strengths**	**Media e.g., Radio**
3.0	**Details of the complaint**		
	Where it appeared		
	When it appeared		
	Supporting documents *Copy of advert (if applicable)*		
	Contact details for feedback and clarification		
	Cellphone		
	Email		
	Signature		
4.0	**FOR OFFICIAL USE ONLY**		
	Complaint Resolved	**Yes** **No**	
	If yes, what was the Verdict		

	If no, what is the next steps		
	Complainant Informed	**Yes** **No**	
	If no, report		
	Name of the Officer.		Date: Sign:
	Checked by Deputy Director.		Date: Sign:

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