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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINE FOR ADVERTISEMENT AND PROMOTION OF HEALTH PRODUCTS AND TECHNOLOGIES

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Table of Contents

ABBREVIATIONS

1. SMPc Summaries of Product Characteristics
2. PILs Patient Information leaflets
3. PARs Public Assessment Reports
4. PPB Pharmacy and Poisons Board (PPB
5. 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 Cap 244 Laws of Kenya.

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

“Board” means the Pharmacy and Poisons Board appointed under the provisions of section 3 of the Pharmacy and Poisons Act CAP 244 Laws of Kenya.

"**Claim**" means any presentation, which 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 objective substation.

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

“General public” means a person other than healthcare workers "General sale drug'' means any drug whose use does not need the direction or prescription by a medical practitioner, dentist or veterinary surgeon.

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.

“Healthcare workers” In case of human drugs it includes members of the medical, dental, pharmacy and nursing profession and any other person who in the course of their professional activity may prescribe, supply or administer a drug or herbal drug and in case of veterinary drugs it includes veterinary surgeons.

‘‘Herbal drug'' means a finished medicinal product containing plant and their preparation presented with 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, 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, the 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 a disease state or the attributes of a product in respect of its therapeutic use that is a use for the purpose of or in connection with;

a) the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof, in man or animal;
b) restoring, correcting or beneficial modification of organic or mental functions in man or animal; or
c) disinfection in premises in which food and drugs are manufactured, prepared or kept, hospitals, equipment and farm houses;

“Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent, software, material or other similar or related article: a) 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 of a physiological process,

c) Supporting or sustaining life, control of conception, disinfection of medical devices, providing information for medical or diagnostic purposes by means of 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;

Medical representative A representative of manufacturing company, importer, distributor or wholesaler licensed by the Board to conduct promotional activities through provision of information on health products and technologies to the general public and healthcare professionals.

Misleading Information- means information that gives a wrong idea or impression

"Marketing Authorization Holder" means an official authorization or registration of a product by PPB for the purpose of marketing in Kenya after evaluation for safety, efficacy and quality.

"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 drug. **"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.

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

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

“Product” for the purpose of this guideline means a medicine, medical devices or herbal drug.

“Promotion” is defined as the 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 and /or sale of the medicines.

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

“Advertisement Committee” means a committee as appointed by the chief executive officer to review and advice on all applications for advertisement and promotion on health products and technologies in Kenya.

ACKNOWLEDGEMENTS

The Pharmacy and Poisons Board (PPB) is particularly grateful to the staff of Product Safety department and other departments who contributed to the successful review of these guidelines.

I take this early opportunity to thank all the stakeholders who participated in the review of the guideline.

1.0 PREFACE

Advertisement and promotion of medicines and medical devices remains an important means of creating awareness and disseminating information to the general public and healthcare professionals.

Advertisement and promotion of health product and technologies remains an important means of creating awareness and disseminating information to the general public and healthcare professionals. Advertising based on sound standards and ethics has many benefits - advertisements provide information about medicinal products, the conditions they treat and what health benefit they can be expected to provide. Advertising refreshes consumer awareness, aids decision making by simplifying choosing a medicine for an identified healthcare need when consumers are pursuing their healthcare requirements, and enhances distinctiveness of specific medicine benefits (e.g., treatment outcomes). Reach is also enhanced through consumer education. Advertising also provides a means of updating society on the latest advances and availability of medicines. Advertisements and promotions can also, if not carried out correctly, mislead consumers and in turn affect their health. Unethical advertisements and advertisements that are based on false claims also negatively affect the lives of consumers.

Over the last two years, there has been a large increase in the number of advertisements and promotions across all mediums and media in Kenya indeed, a welcome activity. However, there has also been an increase in the advertisement of unregistered medicines, medicines with otherwise little safety, quality and efficacy-related data and advertisements and promotions that have not been approved by the Medicines Regulatory Authority- the Pharmacy and Poisons Board. This poses a great threat to the safety of the consumers- something that is unacceptable by the Ministries responsible for Health.

These guidelines have been developed to provide information on the current minimum requirements for authorization to advertise and promote health products, on conventional, alternative, human and veterinary medical products and devices in Kenya. The guidelines stipulate, among other things,

elements of advertisement and promotion, restrictions therein, basic requirements and the application procedures for obtaining approval to advertise and promote.

All are encouraged to be conversant and implement these guidelines in their practice

CHIEF EXECUTICE OFFICER

2.0 INTRODUCTION

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

Pursuant to this mission, it is imperative that the messages communicated to the public and healthcare fraternity helps them
to make an informed decision on the choice and use of drugs determined to be legally available.

These guidelines have been prepared to provide persons involved or wishing to be involved in health products and technologies advertisements and promotions to know which health products can be advertised to the public and the requirements to have them approved by the Pharmacy and Poisons Board.

The success of this initiative will ultimately depend on the active contribution and cooperation of every stakeholder. We trust that all will strive to uphold the standards of practice in medicines advertisement and promotions in Kenya.

This guideline recognises the difference in the level of protection from misleading information necessary for the general public vs health care workers who are subject matters experts that can exercise their professional judgment on information and content. The guidance is designed to be proportionate to the needs of both constituents in healthcare
This guideline will be reviewed regularly based on feedback received from the stakeholders and the changing pharmaceutical industry and regulations. 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 medicines and medical devices advertisement and promotions are concerned.

3.0 LEGAL FRAMEWORK RESPONSIBILITY OF IMPLEMENTATION

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

Subject to the provisions of this Act,

a) No person shall advertise any drug or poison except with the written permission of the Board.
b) Applications for the advertisement of any drug or poison shall be made to the Board in the prescribed form and shall be accompanied by the prescribed fee.
c) No drug or poison or health technology shall be promoted or advertised through any media, including social media, unless it is registered by the Pharmacy and Poisons 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, appliance or article for procuring the miscarriage of women

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

4.0 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

5.0 OBJECTIVE:

The objective of this guideline is to;

a) regularize all advertisements, promotional material and information on health products and technologies available in Kenya
b) articulate ethical criteria for conducting health products promotion activities and comply with applicable legal, regulatory and professional requirements.

6.0 ELEMENTS OF ADVERTISEMENT AND PROMOTION

6.1 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 a medical claim designed to promote the prescription, supply, sale or consumption of medicinal products;
    i. appearing in any paper, newspaper, diary, calendars, or other print publication; business cards or
    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); or
    iv. distributed to the members of the public; branded items or
    v. Press releases subject to editorial discretion / product launches on new chemical entities.
    vi. Telephone help lines and or point of sale materials
    vii. brought to the notice of the members of the general public in any manner whatsoever; with the intention of promoting 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 PPB as an advertisement.

b) the activities of medical representatives including detail aids and other printed material used by representatives to update members of the general public to promote purchase.
c) the provision of branded materials to promote prescription, dispensing, supply, administration and use of products
d) Materials to be used in sponsored meetings.
e) the provision of medical information with product claims to the general public
f) 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.

6.2 What does not constitute advertisement/promotion

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

a) factual, accurate, informative announcements and reference material concerning licensed medicines and relating, for example, to pack changes, adverse reaction warnings, trade catalogues and price lists, provided they include no product claims made to healthcare providers (and not the public).
b) replies made in response to individual enquiries from healthcare workers or employees in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature.
c) Non-promotional information about schedule 2 and above to the general public press conferences, press announcements, television and 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) Issues on pricing, bonuses and incentives governed elsewhere in the law.

7.0 GENERAL REQUIREMENTS FOR PROMOTIONAL ADVERTISEMENT

a) No health product or technology shall be advertised or promoted unless registered or retained by the Board

b) Promotion of off-label and or unregistered indications is prohibited

c) Promotional material sent under the guise of personal communications is inappropriate and unacceptable.

d) The type of audience shall be either public or healthcare providers

e) The content of promotional materials must be balanced., accurate, informative, up to date, in good faith and consistent with information approved during registration of the product;

f) Higher standards shall be applied for the promotion of health products to HCPs than advertisement to the general public. It follows therefore that certain types, styles and methods of promotion to HCPs, even where they might be acceptable for the advertisement to the general public are unacceptable. These include but are not limited to: The provision of private prescription forms pre-printed with the name of a health product, Use of non-technical or scientific language to detail leave behinds leaflets in promoting prescriptions only health products

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

h) Under co-promotion arrangements whereby companies jointly or individually promote the health product each company should

certify the involved promotional material or activity, as they will be held jointly responsible for it under the regulation.

i) Language to be used should be simple to understand and or is likely to bring fear or distress to individuals or community

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

k) Advertisements should not contain statements or visual presentations which is, or 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.

l) Product advertisement material 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.

m) Promotional claim material 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

n) Advertising should not induce unwarranted anxiety among consumers about their condition by suggesting that the condition is of greater severity than is actually the case.

o) Advertising should also not suggest that the condition will deteriorate if the consumer does not use the product or brand featured.

p) Where applicable, appropriate limitations to the use of the medicine should be pointed out.

q) Advertising 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.

r) The content and labelling of advertisements and promotions shall be in trade name; generic name (INN) must appear immediately adjacent to the most prominent display of the trade name

7.1 SPECIFIC REQUIREMENTS

7.2 Advertisement to the general public

a) Part II Poisons are permitted to be advertised to the general public in any form of the media.

b) Part I Poisons may not be advertised to the public however, the use of point-of-sale advertising materials, such as dummy boxes maybe be used within the confines of the pharmacy.

c) Controlled, narcotic and psychotropic substances shall not be advertised to the general public in any format.

d) It is illegal to direct any advertisement or promotion to the public that is likely to lead to the irrational use and misuse of part I and part II Poisons

e) Price list for Part I Poisons may be advertised to the public provided no indications/claims are made

f) Exempted from this provision is the advertisement or promotion of a licenced vaccine approved by the board or granted emergency use authorisation 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.

7.3 Promotion to the healthcare practitioners

a) Promotional advertisements on Part I and Part II poisons shall be directed towards the healthcare practitioners qualified to prescribe, dispense, handle or supply medicines.

b) The wording and illustrations shall be technical and fully consistent with the latest scientific data.

c) Dissemination of latest scientific or clinical information to healthcare professionals on part I and Part II shall be done by personnel from regulatory department and not marketing department.

7.4 Promotion and advertisement of medical devices

a) Medical devices that 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 should 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 brough about or associated with ageing

e) Medical devices with supply restrictions must feature the restrictions on the advertisements

f) Marketing materials should not suggest that the medical device will prevent, alleviate, or cure

g) It should not imply that the medical device can induce sexual performance or they are effective in treating sexual weakness or excess and conditions such as premature ejaculation and erectile dysfunction.

7.5 Herbal and complementary medicine

a) It shall be promoted or advertised after issuance of an approval by the Board

b) Indications can be based on evidence of traditional use of a substance or product, and/or on scientific evidence. Indications/claims are categorised depending on the level of claim being made.

c) All indications must be true, valid and not misleading, and should not lead to unsafe or inappropriate use of the product.

d) Evidence must relate to the whole product or the same active ingredient(s) with similar dosage regimen, dose form and route of

administration to the product/ingredient for which the claim is being made.

e) Evidence must be available before claiming an intended use or indication for a product. Claims and the levels and kinds of support must be in accordance with the Guidelines for Complementary Medicines.

f) The 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

g) 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.

h) All herbal medicine and related products advertisement shall strictly be in line with claimed indications as registered or listed by the board.

i) Cautionary labels or disclaimer statements must be displayed on the label of advertisement materials of herbal medicine and related products.

j) Advertisement for herbal and related products shall not contain such words as "magic" "miracle" or an exotic description such as "upper potency" or such other words as to induce the daily or continuous use of the product;

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

l) The use of terms clinically proven or effective are not permitted since registration of products are based exclusively on long standing use

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

n) Advertising which states or implies that a product is "safe" is unacceptable. Advertising should not suggest that a product does

not have any side-effect or that its safety or efficacy is due to the fact that it is natural, nor should it include any description or detailed representation of a case history that may lead to erroneous self-diagnosis.

7.6 Vitamins

a) No advertisement should state or imply that good health is likely to be jeopardised 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.

7.7 Weight management

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

b) Slimming/Body image, fat burning, fat and starch blocking which include direct or implied claims or imply efficacy. All references should be linked, by means of 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

8.1 Pregnant and lactating women

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

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

c) Where there is suggestion for use of a product in pregnancy, all advertisements must encourage a cautious approach before use and

include a statement that women should consult their healthcare professional before use.

8.2 Children and minors

a) Advertising and/or promotion shall not be aimed principally or exclusively at children (under the age of twelve years).
b) Advertising and/or promotion shall not show children using, or within reach of, health product 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

9.1 Public advertisement

a) the generic name of a drug, brand name/trade name of the drug, name(s) of the active ingredient(s) using International Non-Proprietary Names (INN),
b) approved indication(s) for use, and major precautions, contra-indications and warnings.
c) dosage regimen and maximum allowed daily dosage in cases of herbal and complementary medicines.
d) Phrase “Maumivu yakizidi pata ushauri wa daktari” or “If symptoms persist seek medical advice” or a similar meaning phrase.
e) Printed materials should be clearly labelled “for public only”.
f) The contact details of the Market Authorisation Holder should always appear on every print media

9.2 Promotions to HCPs

a) the name of the active pharmaceutical ingredient(s) using either international non-proprietary names (INN) or the approved generic name of the drug; the brand name;
b) content of active ingredient(s) per dosage form or regimen;
c) name of other excipients known to have an effect;
d) approved therapeutic uses; dosage form or regimen;

e) side-effects and major adverse drug reactions; precautions, contra-indications and warnings;
f) major interactions;
g) Reference to the current scientific literature as appropriate.
h) Contact details of the Market Authorisation Holder / name and address of manufacturer or distributor should always appear on every print media.

10.0 ETHICAL ADVERTISEMENT

a) There should be no personal enrichment of healthcare professionals or other healthcare providers. 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.
b) When in conflict with product posology, bonus offers, free samples, including for competitions, and discounts offered directly to the general public are not permissible.
c) Healthcare professionals should not ask for or accept any material rewards from companies, organisations 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
d) Advertising to the general public 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. Material which 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
e) Advertising to the HCP should 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

f) Promotion should not be disguised. Clinical assessments, post-marketing surveillance, experience programs and post authorization studies must not be disguised as promotion or advertisement. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which are sponsored by a company or distributor/importer should clearly indicate by whom it has been sponsored.

11.0 HEALTH PRODUCTS FREE SAMPLES

a) The supply of a free sample of a licensed health product shall be made by the authorised medical representative to a dully qualified and registered healthcare practitioner for the purpose of acquiring knowledge and experience in dealing with the product.

b) There should be no sale or supply of samples of health products or medical devices to any member of the public

c) samples may only be supplied to a person qualified to prescribe medicinal products, and 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

   ii. they shall be no 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.

d) Samples shall not be supplied to persons qualified only to dispense and supply medicines.

e) Medical Representatives and recipients shall maintain an adequate system of control and accountability of all product samples except for controlled substances

f) The pharmacist In-charge shall be responsible to maintain control and accountability of all samples for controlled substances submitted for purposes of bidding for tenders and listing into the hospital formulary.

g) 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/companies wishing to promote/advertise health products, medical devices or services through the websites/portals shall conform to the following requirements;

12.1 General requirements for online advertisements and promotions

The fundamental requirements for promoting and advertisement via 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) Advertisement and promotion through social media platforms shall be limited to all general sales products and technologies

b) The online platform shall be operated, maintained and supervised by a registered pharmacist or enrolled pharmaceutical technologist

c) The content of the ecommerce platform must not contravene the guideline and Cap 244

d) Advertisement using social media accounts belonging to government agencies, professional associations, celebrities and social media influencers is 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 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.

h) Approved materials to the general public shall be uploaded to any portals or websites by the third party only after authorization from the MAH.

i) The MAH shall be withdraw these advertisements from the sites upon expiry of their validity period.

12.2 LICENSED ONLINE PHARMACY

a) Online website providing dispensing services aimed specifically at patients who already have a prescription, provided no product claims are made shall 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 general sale health products with prices,

c) Advertisement or promotion of POM products on online pharmacy websites is prohibited however factual, accurate and scientific information can be shared or posted.

d) General sale health products shall be advertised

e) Images of POM products shall not be displayed however trade names and indicative prices shall be displayed.

12.3 COMPANY/ORGANIZATIONS WEBSITES AND PORTALS

Companies or organizations 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.

12.4 Window for the general public

a) The general public platform shall be used to advertise general sales health products, medical devices and services without promoting POM health products

b) The Home/landing page should focus on general sales health products and the services the website/platform provides and should not include any reference to named POMs, including price information. Links and navigation aids may be given for particular services and information but not to specific POMs.

c) Text and any small print or advertisements at the bottom of the home page should also not refer to specific POMs. This provision is designed to ensure that casual browsers are not presented with advertising for specific POMs.

d) Further pages about the health products, which the consumer chooses to access, may 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. 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.

f) 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.

12.5 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 / 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.

f) Each section of the journal promoting medical products and technologies shall be clearly labelled "intended for healthcare practitioners only"

12.6 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 and should not encourage the general public to ask their health practitioners to prescribe the product.

b) The use of brand names should be kept to a minimum and the tone and content of the press release must be factual and not sensationalised.

c) When responding to enquiries from the public about prescription only medicines, companies should ensure that such responses are factual, non-promotional and limited to the subject matter of the enquiry.

13.0 PROMOTIONAL MEETINGS

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

b) No product promotional meeting or any other meetings or gathering including workshops, conferences, seminars, symposia, awareness campaigns, exhibitions organized or sponsored by any company where a medical product or health technology may be promoted to the general public or healthcare professionals shall be held without approval from the Board

c) Any person wishing to conduct such meetings shall submit to the Board an application in the prescribed format at least four weeks before the meeting

d) Promotional meetings directed at the general public with a view to providing information, awareness or educating the public about a particular condition or disease shall be acceptable as long as no direct reference to a brand or product is made by use of brand names, restricting the range of treatments described in the campaign or drawing attention to the campaign by advertising which is likely to lead to the use of a specific prescription only medicine or medicines

e) Contents of presentation at symposia shall be factual, accurate, without omission and not biased towards any particular company's products;

f) Sales of product during such meetings or trade shows where drugs are exhibited is prohibited;

g) Advertisements for mass immunization as part of a national government immunization or vaccination campaign shall be done using the generic (INN) name.

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 an 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 may 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) Application procedures for a licence to conduct promotion meetings are as follows;

   i. Applications should be made by filling in the application form as prescribed in **Annex I**

   ii. The application should be accompanied by prescribed fee and samples of all materials and products or branded items to be used in the meeting for advertisement or promotion.

14.0 STAKEHOLDER RESPONSIBILITIES

14.1 Marketing Authorization Holders (MAH)

a) MAH shall be responsible to ensure that their products conform with quality, safety and efficacy standards and are registered or retained by the Board before they subject them to promotions and advertisements.

b) Companies shall be responsible to provide product education and training available to HCPs in the interest of ensuring the appropriate, safe and effective utilisation of a particular type of medical technology.

c) MAH should ensure that their medical representative's and marketing team refrain from illegal and an authorized practices in relation to product promotional activities

d) MAH should ensure that the information provided about their respective products are correct and in accordance with the PPB regulations and guidelines.

e) Companies should ensure compliance with the following requirements if they are considering becoming involved in any patient support program: -

a) No incentives, other than material that will enhance positive health outcomes and compliance, are provided to patients to become involved in these programs;

b) The data collected from these programs will not be used for any purpose other than to increase positive health outcomes and never for promotional activities; and
c) The duration of these programs is appropriate to the disease state treated by the product involved.
f) MAH are also obliged to report any contraventions of the laws and regulations and be ready to collaborate and cooperate in sharing information.

14.2 County Governments

a) The county governments in collaboration with the County Pharmacists shall report any contraventions related to advertisement and promotion of health products and technologies.
b) The county executive committee (CEC) members shall be responsible in ensuring rational use of health products and technologies and report any misuse and abuse to PPB regional and national office.
c) The county executive committee (CEC) members shall be responsible in ensuring rational use of health products and technologies and report any misuse and abuse to PPB regional and national office.
d) The county governments in collaboration with the County Pharmacists shall report any contraventions related to advertisement and promotion of health products and technologies
e) The county executive committee (CEC) members shall be responsible in ensuring rational use of health products and technologies and report any misuse and abuse to PPB regional and national office.
f) The county executive committee (CEC) in collaboration with the PPB regional offices should sensitize and create awareness on the laws and regulations that govern advertisement and promotion of health products and technologies.

g) They shall assist the Board in recording, reporting, and forwarding stakeholders complaints relating to promotion and advertisement of health products.

14.3 Health care professionals

a) They shall 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.

14.4 Media

a) They shall only promote products that have been registered, retained and granted approval by the Board for advertisement.

b) They shall reject advertising and promotional materials without an approval from the Board

c) They shall comply with the requirements of CAP 244, other regulations and guidelines for advertisements and promotions and report and contraventions on the said laws

d) They shall convey information that is factual and accurate as per the approved sample materials or scripts.

e) They shall collaborate with PPB in enforcing the law and sharing of information, complaints and concerns related to health products advertisements.

f) They shall assist the Board in sharing recommendations and comments on how to regulate, control and promote health products advertisements

14.5 Communication Authority of Kenya (CAK)

a) Collaborate with the Board in Monitoring the activities of e commerce licensed entities promoting advertisements and marketing of health products.

b) To 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.

14.6 General Public

a) They shall request correct and scientific information from the Board on the quality, safety, efficacy, registration or listing of health products and technologies.
b) They shall 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) They shall participate in the review process of guidelines related to advertisements and promotions.
d) They shall collaborate with the Board by sharing any

15.0 GUIDELINES ON CLAIMS, REFERENCES AND COMPARISONS

15.1 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.

15.2 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.

15.3 Comparisons

a) Comparisons must 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 against which the health product is compared;

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 should 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.

16.0 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 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.

17.0 APPLICATIONS AND REVIEW PROCESS

a) All applications shall be made through the Pharmacy and Poisons Board Portal for that have been listed in PPB 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 attached as **Annex II** and accompanied with relevant information as detailed in these guidelines.

b) Any application uploaded into the portal without payment within 30 days shall be removed
c) All application, fees shall be charged per product per media and paid through Mpesa or at the PPB offices through cheques or bank transfer to the Pharmacy and Poisons Board accounts
d) Once the application has been accepted and evaluation fees paid, review of the application by reviewers shall take a maximum of 15 working days.
e) All application shall be subjected to a plenary evaluation by the advertisement and promotion committee appointed by the Chief Executive Officer.

17.1 Screening checklist for manual and online application

a) Proof of up-to-date registration of the company that wishes to advertise with the PPB;
b) Proof of up-to-date 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) in the health product in INN
f) List of current scientific references
g) Registration number and current physical address of the MAH printed on the sample material except for branded items
h) Type of audience printed on the sample material except for branded items (for public only or for HCP only).

17.2 PPB advertisement portal

The following documents shall be uploaded in the online advertisement portal.

a) TV advertisement- detailed story board 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

17.3 Manual Applications

The following documents shall be submitted in case of manual submission

a) One CD copy of the final advertisement
b) Six copies of script for TV, Radio or social media advertisement
c) three copies of final samples/artwork
d) three samples of the branded items

17.4 Requirements

a) All CDs submitted should be CD-R discs.
b) Documents such as video clips should be viewable via Windows Media Player compatible with Windows 2000 version and thereafter.
c) Conditional approval shall be upon review of storyboard/script prior to airing, following which full approval shall be granted upon submission of the final prepared advertisement

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, consumption or 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.

However, advertisements for the above aimed at members of the National Assembly, members of the governing body of a voluntary hospital, duly qualified medical practitioners, dentists and veterinary surgeons, registered pharmacists, authorized sellers of poisons and licensed wholesale dealers, persons carrying on a business which includes the sale or supply of surgical appliances, or an advertisement in connection with an application for a patent submitted to the appropriate authority so far only as was requisite for the purpose of the application shall be exempt from the prohibition

17.0 APPEALS

a) Any person aggrieved by a decision of the Board in relation to any application for advertisement or promotion of medicines or medical devices may make representations in writing to the Chief Executive Officer.
b) If after consideration of the representations, the Board is satisfied it may approve the advertisement or promotion of medicine or medical device and if not satisfied it shall reject the application.
c) An appeal shall be lodged within 30 working days of the Board's official communication.

18.0 VALIDITY

a) The Board shall, if satisfied that the proposed advertisement or promotional material complies with the requirements prescribed in these regulations, issue an approval letter or conditional letter to the applicant.
b) A reference number will be quoted for each approval. The applicant is required to quote this reference number whenever any correspondence is made regarding that advertisement or promotion
c) All approved advertisements and promotions are valid for one year from date of approval.
d) It shall be the responsibility of the Marketing Authorisation Holder to either withdraw all advertisement and promotional materials from

the market upon expiry of the stated validity or reapply to the board for continued advertisement/promotion of the same.

19.0 OFFENCES, PENALTIES AND ENFORCEMENT

19.1 OFFENCES AND PENALTIES

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

a) Pharmacy and Poisons Act, CAP 244 and section 51, Laws of Kenya,
b) Regulatory actions
c) Disciplinary actions.

19.2 ENFORCEMENT

Compliance to this guideline and the law shall be enforced by the PPB authorised pharmaceutical Inspectors in collaboration with the National Police Service, Pharmacy and Poisons Board Disciplinary Committee and the Director Product Safety department.

20.0 COMPLAINTS AND FEEDBACK

a) All complaints should 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 attached as **Annex III** the form can be obtained from PPB headquarters and regional offices or through the PPB website www.pharmacyboardkenya.org
d) Complaints should 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 done within thirty (30) working days and should the investigation take longer, the complainant will be updated.

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

21.0 REVIEW OF GUIDELINES

a) This guideline will be reviewed regularly (every three (3) years or as required) based on feedback received from the stakeholders and the changing pharmaceutical industry and 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 medical devices advertisement and promotions are concerned.

22.0 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

3.0 Zambia first edition April, 2008.

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

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

23.0 Revision History

Pharmacy and Poison Board	**Revision History**			**HPT/PDS/GUD/046**
Rev No. 1	**Date 26/01/2022**	**Prepared By: MIO**	**Sections Revised**	**Description of change**
Rev No. 1	26/01/2022	MIO	all sections	Edited to comply with QMS requirements

			Citation page	Introduced citation page
			Glossary	Added definition of claim, dispense, HPTs, label, medium, medical representative and new chemical entity
Rev No. 1	26/01/2022	MIO	2	Introduction of the guideline
Rev No. 1	26/01/2022	MIO	3	Introduced legal framework
Rev No. 1	26/01/2022	MIO	6.0-6.2	Introduced elements of advertisements
Rev No. 1	26/01/2022	MIO	7.0-7.7	Introduced general and specific requirements for advertisements to general public, Healthcare workers, medical devices, herbal and complementary, vitamins, weight managements
Rev No. 1	26/01/2022	MIO	8.0	Introduced advertisements to special population; children and pregnant women
Rev No. 1	26/01/2022	MIO	10.0	Introduced ethical advertisements; i.e., bonuses and gifts

24.0 CONTRIBUTOR'S

1. Dr. Fred Moin Siyoi- CEO, Pharmacy and Poisons Board
2. Dr. Ahmed Mohamed- Director, Health Products and Technologies,
3. Dr. Wilfred Ochieng- Director, Pharmacy Practice, PPB
4. Dr. Jacinta Wasike- Director, Corporate Affairs, PPB
5. Dr. Peter Mbwiiri Ikamati- Products Evaluation and Registration,
6. Dr. Kariuki Gachoki-Deputy Director, Product Services, PPB
7. Dr. Nancy Cherotich-Medicines Information, PPB
8. Dr. Christabel Khaemba- Pharmacovigilance and PMS, PPB
9. Dr. Karim Wanga- Pharmacovigilance and Post Market Surveillance,
10. Dr. Martha Mandale- Pharmacovigilance and PMS, PPB
11. Dr. Pamela Nambwa- Pharmacovigilance and PMS, PPB
12. Dr. Onesmus Saidimu-Pharmacovigilance and PMS, PPB
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,

25.0 ANNEXES

Annex 1: Application form for approval to conduct promotion meetings

PHARMACY AND POISONS BOARD

Application for approval to conduct promotional meetings

All information supplied in this form must be typed and submitted manually or electronically to the Chief Executive Officer Kenya Pharmacy and Poisons Board, Lenana Road, Nairobi.

1. **Applicant Information**

Name of applicant	
Registration number	
Cadre	
Telephone	

2. **Type of promotional meetings**

Workshops	
Conference	
Seminar	
Exhibitions	
Symposia	
Others	

3. Company/ Sponsor Information

Name of company/sponsor:	
Registration No	
Contact person	
Telephone	
Email	
Physical address:	
Building	
Street/Road	

4. Products promoted (attach list and media for each)

	Product	**Registration No**	**Media**

5. Responsible Person Information (if different from applicant)

	Name of the officer	
	Registration No	
	Cadre	
	Telephone	

6. Date and Venue:

	Date	**Start Date:** **End date**	**Time:** **Time**
	Name of the venue		
	Physical address		
	Building		
	Street/ Road		

Annex 1I: Application form for approval of promotion materials

PHARMACY AND POISONS BOARD

Application for approval of promotion materials

Pharmacy and Poisons Board	**Application form**	**FOM017/MIR/SOP/006**	
		Rev No	
1.0	**Company Details**		
	Name of company		
	Registration No		
	Physical address		
	Building		
	Street/Road		
2.0	**Applicant Information**		
	Name of applicant		
	Registration number		
	Cadre		
	Telephone		
3.0	**Responsible Person Information**		
	Name of the officer		
	Registration No		
	Cadre		
	Telephone		
4.0	**Product Particulars**		
	legal category	**Product**	**Reg No**	**Type of Media**

5.0 **Application check list**	
A copy of the proposed advert	
Proof of payment	
Copy of reference materials	
Copy of previous approval	
6.0 Applicant Declaration	
.....declare that the information contained within this application is true and correct.	**Date .....**
	Sign.....

7.0 FOR OFFICIAL USE ONLY		
Product	Approval granted	Rejection granted
Reason for Rejection		
Name of officer	**Date**	

Annex III: Complaint form

PHARMACY AND POISONS BOARD

Complaint form

This form should be sent to the Chief Executive Officer, Pharmacy and Poisons Board, Lenana Road.

1.0 Complainant/ Reporter details (optional)

	Name of the person/Company/Organization	
	Building	
	Street/Road	
	Email	
	Telephone	

3.0 Product Details

	Product Name	**Strengths**	**Dosage form**	**Media e.g., Radio,**

4.0 Content of the complaint

	Narrative of the complain	
	Where it appeared	
	when it appeared	
	Supporting documents *Copy of advertisement and promotion (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		
	If no, report		

Name of the Officer		Date Sign
Checked by Deputy Director		Date Sign

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