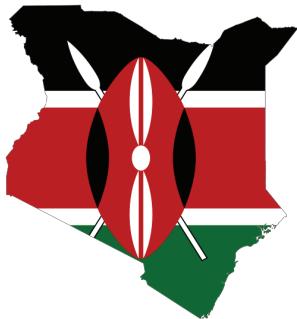




REPUBLIC OF KENYA
PHARMACY AND POISONS BOARD



- ✓ Convulsive Cough
 - ✓ Catarrh and
 - ✓ Hoarseness
- with accumulation of tenacious mucus in the throat.



**GUIDELINES FOR ADVERTISEMENT AND PROMOTION OF
MEDICINES AND MEDICAL DEVICES IN KENYA**

First Edition
April 2012

Aim:

The guideline is aimed at ensuring that all information communicated to health care practitioner and the general public is accurate, current, factual and not misleading in anyway.

Scope:

This guideline applies to all manufacturers, wholesale dealers and all wishing to advertise or promote medicines or medical devices in Kenya. The criteria are applicable to both prescription and non-prescription medicinal drugs, both for human and veterinary use.

It also applies to traditional, herbal and other alternative schools of medicines and any other product promoted as a medicine.

This guideline applies to all advertising and promotion material for medicines in Kenya, and to information made available to the general public or any other interested person about medicines so advertised or promoted.

Objective:

The objective of this guide is to regularize all advertisements, promotional material and information on medicines available in Kenya and articulate ethical criteria for medicinal drug promotion in order to support and encourage the improvement of pharmaceutical care and promote rational use of medicines. The information thus provided should enable the health care professional and the patient in making rational decisions in the use of medicines.

This guideline will be used in conjunction with The Pharmacy and Poisons Act, Chapter 244, 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.

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.

Foreword

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

Advertisements and promotions can also, if not carried out correctly, pass the wrong information and in turn affect the health of the consumer. Unethical advertisements and advertisements that are based on false claims also affect the lives of the 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 medicines, 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.



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Preamble

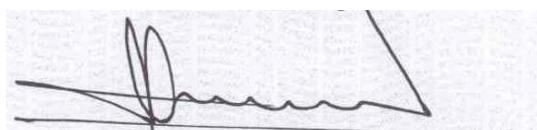
The Pharmacy and Poisons Board is committed in its mission to ensure the advertisements and promotions of medicines in Kenya are done within the legal framework and that the messages sent to the public and healthcare workers remains factual, evidence based and not misleading.

Pursuant to this mission, it is imperative that the messages communicated to the public and healthcare fraternity helps 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 medicines advertisements and promotions to know which medicines 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. I trust that all will strive to uphold the standards of practice in medicines advertisement and promotions in Kenya.

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.



**Dr. Kipkerich C. Koskei, OGW
REGISTRAR.**

Acknowledgements

The Pharmacy and Poisons Board (PPB) is particularly grateful to the following for their support in the preparation of this guideline:

- The Ministry of Medical Services
- The Ministry of Public Health and Sanitation
- Our stakeholders, partners and clients

We take this early opportunity to thank all the respondents who offered their valuable contributions to the editing of this guideline.

Gratitude is extended to the Chairman, Secretary and all members of the Executive Board and entire Secretariat who offered contributions towards development and production of this document.

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The Pharmacy and Poisons Board acknowledges the immense contribution of the following for their research, compilation and commitment in developing this guideline:

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Definitions

“Applicant” means a person 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;

“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;

“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;

“Drug” includes any medicine, medicinal preparation or therapeutic substance including herbal drugs.

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

“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;

“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 activities may prescribe, supply or administer a drug or herbal drug and in case of veterinary drugs it includes veterinary surgeons;

"Herbal drug" means any labeled preparation in pharmaceutical dosage form that contains one or more substances of natural origin as active ingredients that are derived from plants.

"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

"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;

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

"Medical device" health or medical instruments used in the treatment, mitigation, diagnosis or prevention of a disease or abnormal physical condition.

"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;

“MAH” 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. New active pharmaceutical ingredient: Means a drug (active ingredient), including its salts and/or esters.

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

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

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

“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” means a drug, 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 usage of a product.

“Registrar” means the Registrar appointed under the provisions of section 5 of the Pharmacy and Poisons Act CAP 244 Laws of Kenya;

“Advertisement Committee” means a committee as appointed by the registrar to review and advice on all applications for advertisement and promotion on medicines and medical devices in Kenya.

Elements of Drug (Medicines) Advertisement and Promotion.

- (1) Any activity undertaken in the manner provided hereunder shall constitute drug promotion:
- (a) Advertising: including any written, pictorial, visual or other descriptive matter or verbal statement or reference-
- I. appearing in any paper, newspaper, diary or other print publication; or
 - II. appearing on any television, cinema, radio, internet; 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; or
 - V. brought to the notice of the members of the public in any manner whatsoever; which leads to the promotion of the sale of that medicine;
 - VI. branding on vehicles, buildings, benches and other similar media;
 - VII. road shows and other similar means; and
 - VIII. Any other means that may be considered by the PPB as an advertisement.
- (b) the activities of representatives including detail aids and other printed material used by representatives to update members of the public
- (c) the supply of samples to the public
- (d) the provision of inducements to prescribe, dispense, supply, administer, recommend or buy products through gifts, offer or promise of any benefit or bonus, whether in money or in kind
- (e) 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,.

- (f) the sponsorship of promotional meetings aimed at the public
 - (g) the provision of information to the general public either directly or indirectly
 - (h) all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, radio, television, internet, electronic media, interactive data systems and the like.
- (2) Unless the context states, the following activities shall not form drug advertisement and promotion;
- (a) replies made in response to individual enquiries from healthcare workers or employees in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry, are accurate and do not mislead and are not promotional in nature (see (1) above).
 - (b) 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).
 - (c) Summaries of Product Characteristics (SPCs).
 - (d) The labelling on medicines and accompanying package leaflets insofar as they are not promotional for the products concerned; the contents of labels and package leaflets are covered by regulations.
 - (e) Statements relating to human health or diseases provided there is no reference, to a specific product.

Core principles of advertisement:

- *Basis of interaction:* A relationship with healthcare professionals is intended to benefit patients and enhance the practice of medicine; interactions should be focussed on informing health professionals about products, providing scientific and educational information and supporting medical research and education.
- *Independence of healthcare professionals:* healthcare professionals should not be influenced to prescribe, recommend, purchase, supply or administer a product because of any benefits offered (financial or otherwise).
- *Appropriate use:* promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggeration.
- *Local regulations:* all relevant laws, local regulations and industry codes must be observed.
- *Transparency of promotion:* all company sponsored material related to pharmaceutical products and their uses should clearly indicate by whom it has been sponsored; clinical assessments, post-marketing surveillance and experience programs and post-authorization studies must be conducted with a primarily scientific or educational purpose.

Requirements for advertising.

1. No person shall advertise any medicine except with the written permission of the Pharmacy and Poisons Board
2. No product shall be promoted unless it is registered by the Pharmacy and Poisons Board;
3. Advertisements should be accurate, factual up-to-date, reliable, truthful, informative, balanced, and capable of substantiation and in good faith.
4. All packaging and labelling materials shall provide information which is consistent with that approved during the registration of the product;
5. Bonus offers and discounts offered directly to the public are not permissible.
6. Claims of superiority over other brands will not be permitted.
7. Once an advert has been approved, no changes however small can be made to it without approval of the Board.
8. Companies must provide evidence of acceptance to use some information on their adverts e.g music clips from tracks by artists.
9. Adverts should clearly inform the public about the risks associated with the use of the product e.g Use of aspirin containing products may lead to peptic ulcer diseases.

Content of Advertising or Promotional Material

- 1.The content of promotional materials must be unbiased, accurate, informative, up to date, in good faith and consistent with information approved during registration of the product;
- 2.Promotional 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;
- 3.Advertisements/promotions should not contain misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or give rise to undue risks.
4. Advertising and/or promotion shall not be aimed principally or exclusively at children (under the age of twelve years).Advertising and/or promotion shall not show children using, or within reach of, health product without adult supervision.
5. Where applicable, appropriate limitations to the use of the medicine should be pointed out.
6. Language that brings about fear or distress should not be used.
7. No product shall be promoted in a manner that is misleading or calculated to mislead, deceptive or is likely to create erroneous impression either directly or by implication regarding its character value, quantity, composition, safety or efficacy as the case may be;
8. No offers of free samples, including for competitions, directed at the public should be made.
9. No product endorsements by medical professional bodies like KMA, PSK etc.

Restrictions on Advertisements

- a. No person shall use any promotional material to advertise any product (Both human and Veterinary) unless he/she applies and is issued with a written approval from the Board to the general public.
- b. An advertisement to the general public shall not refer to an Act, or any department or official of the Board.
- c. Every application for an advertisement or a permit to use a promotional material shall be made to the Board by submitting an application to the Registrar, Pharmacy & Poisons Board in the prescribed format and paying the prescribed appropriate fee (See attached requirements to submit an advertisement).
- d. Advertisement of medicines to the public is NOT permitted if it is in terms calculated to lead to their use in human beings for any of the following conditions:
 - i. The cure of amenorrhoea, gonorrhoea, HIV-AIDS, syphilis, or soft chancre in any of their forms, and other sexually transmitted infections.
 - ii. 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.
 - iii. The prevention, relief or cure of blindness, Bright's disease, schistosomiasis, and cancer, malignancies.
 - iv. The cure of alcoholism, appendicitis, arteriosclerosis, bladder stones, cardiovascular disease, cataract, diabetes, diphtheria, dropsy, epilepsy or fits, gallstones, gangrene, glaucoma, goiter, heart disease, hernia, hypertension, hypotension, infantile diarrhoea, kidney stone, leprosy, locomotors or other ataxia, lupus, meningitis, multiple sclerosis, nephritis, osteoarthritis, paralysis, Parkinson's disease, plague, pleurisy, poliomyelitis, pneumonia,

prostate gland disorders, rheumatoid arthritis, rheumatic fever, scarlet-fever, small pox, septicaemia, tetanus or lock-jaw, thrombosis, tuberculosis.

- v. The use of medicines to reduce or add weight or alter any other body functions apart from what is scientifically proved.

Approval of Advertisements or Promotional Materials

1. The Board shall, if satisfied that the proposed advertisement or promotional material complies with the requirements prescribed in these regulations, issue an approval letter to the applicant.
2. The approval is valid for 1 year from the date the approval is given.

Advertisements to Healthcare Workers

Advertisement to healthcare workers shall contain at least the following information which should be consistent with the approved summary of product characteristics:

- a) The brand name/trade name;
- b) The name(s) of the active ingredient(s) using either international nonproprietary names (INN) or the generic name of the drug;
- c) Content of active ingredient(s) per dosage form or regimen;
- d) Name of other ingredients known to cause adverse or other effects;
- e) Approved therapeutic uses;
- f) Dosage form or regimen;
- g) Side-effects and major adverse effects;
- h) Precautions, contra-indications and warnings;
- i) Major drug-drug or drug-food interactions;
- j) Name and address of manufacturer and applicant;
- k) Reference to scientific literature as appropriate.

Advertisement to the General Public

1. Advertisement targeted to the general public must contain the following:

- (a)the generic name of a drug, brand name/trade name of the drug
- (b) name(s) of the active ingredient(s) using international non proprietary names (INN)
- (c)approved major indication(s) for use
- (d) major precautions, contra-indications and warnings
- (e)name and address of market authorization holder
- (f) dosage regimen
- (g)Phrase “Maumivu yakizidi pata ushauri wa daktari” or “If symptoms persist seek medical advice” or a similar meaning phrase

2.Advertisement to the general public shall take into consideration the following:

- (a)Help people to make an informed decision on the choice and use of drugs determined to be legally available without a prescription.
- (b) Take account of people's legitimate desire for information regarding their health.
- (c)that a product has PPB / WHO or any other similar “approval”.

Web based Advertisement of Medicines

There shall be no direct advertisement to the general public of the Prescription only Medicines as stipulated in CAP 244 laws of Kenya.

Advertisements for POMs are acceptable only on websites whose nature and content are directed at health professionals. Sections of a website aimed at health professionals and containing promotional material should ideally be access restricted.

If no restriction is applied and websites provide both information for consumers and information aimed at health professionals that includes advertising, the sections for each target audience should be clearly separated and clearly marked for the respective target audience.

For persons or institutions/companies wishing to give information through the website, there shall be two windows; one for the health professionals and another for the general public.

The type and amount of information given in the general public window should not contravene any section of CAP 244. There shall be no promotion of prescription medicines to the general public through this window. One may list the names of the prescription medicines. This can be accompanied by limited information as contained in the Patient Information Leaflet. Additionally there shall be a declaration that the medicine can only be got under a prescription from a registered medical practitioner and self-prescribing is not recommended on each window / section of the document viewed.

A journal which is published or posted on the internet and which is expressly stated to be for health professionals is considered to be directed at persons qualified to prescribe or supply medicines and the advertising contained within the journal should comply with the law. Each page of an advertisement for a prescription only medicine (POM) should be clearly labeled as intended for health professionals.

Disease awareness and health education campaigns

Campaigns relating to human health directed at the general public with a view to providing information, promoting awareness or educating the public about a particular condition or disease are encouraged. Care must be taken to ensure that the information provided does not make product claims for the material to remain outside the definition of an “advertisement” under the Regulations.

In particular, 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 is not allowed.

Recommendations and endorsements

Advertisements to the general public should not contain material which refers to recommendations by scientists or health professionals, or which refers to recommendations by celebrities or well known organizations who, because of their celebrity status, could encourage consumption of products.

Advertisers 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.

Restrictions on Advertising to the General Public

1. Product advertisement material should not contain pictures of sexual organs or any other morally unacceptable images to the greater public. Pictures other than those prohibited may be used on adverts but they must be aesthetic, not objectionable and consistent with Kenyan culture.
2. No person may advertise to the general public any drug other than general sales drugs only;
3. Language that brings or is likely to bring fear or distress to individuals or community is prohibited;
4. Use of healthcare workers or persons purporting to be healthcare workers in promoting medicines is prohibited.

5. Advertising and/or promotion shall not be aimed principally or exclusively at children (under the age of twelve years). Advertising and/or promotion shall not show children using, or within reach of, health product without adult supervision.
6. Promotion should not be disguised. Clinical assessments, post-marketing surveillance, experience programs and post-authorization studies must not be disguised promotion. 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.

Outline of Evaluation Process

The manufacturer or the market authorization holder is required to apply for the advertisement or promotion at the Pharmacy and Poisons Board two weeks before the scheduled advertisement committee meeting.

Only products with a valid Registration certificate will be allowed to be advertised or promoted.

The local authorized representative is explicitly designated by the manufacturer, to act and to be addressed by PPB in Kenya on their behalf, with regards to the latter's legal obligations and responsibilities.

The PPB will briefly review the application in concern and it will decide if it will be either exempted from further evaluation or otherwise issue the applicant with an official letter requesting submission of more documents.

The decision will be made according to set criteria.

Timelines

Once an application has been accepted and evaluation fees paid the processing of application will take a maximum of 30 working days. This will involve evaluation of application, request for additional information and clarification of some issues where applicable.

Advertisement and Promotion of Medical Devices

Only medical devices registered in Kenya shall be advertised and/or promoted. Where an advertisement relates to the merits of a device used for administering medicines, such as an inhaler, which is supplied containing a variety of medicines, the prescribing information for one only need be given if the advertisement makes no reference to any particular medicine.

If such a reference is given to a particular medicine then full prescribing information must be included in relation to each particular medicine referred to.

Advertisement on Promotional Aids

- 1.A promotional aid (note pads, calendars and other such items) shall be limited to bear names of drugs currently registered in Kenya. If a promotional aid in which the individual pages bear advertising material, there is no need for the individual pages to comply with the above requirements provided that such required information is given elsewhere; for example on the cover.
- 2.Both the proprietary and established names should be included on the promotional aid, though a promotional aid may bear the names of more than one medicine.

Symposia

1. No product promotional meeting or any other meetings or gathering where a drug or herbal drug may be promoted to the general public shall be held without notifying the Board at least four weeks before the meeting by the organiser/MAH.
2. Any person wishing to conduct such meetings shall submit to the Board an application in a prescribed form;
3. Presentation at symposia shall be factual, accurate, without omission and not biased towards any particular company's products;
4. Sales of product during such meetings or trade shows where drugs are exhibited is prohibited;

Medical and Pharmaceutical Representatives

Medical and pharmaceutical representatives carry out promotional activities on behalf of manufacturers and distributors. The manufacturers and distributors should submit applications for authorization of their medical representatives to the Pharmacy and Poisons Board. The Pharmacy and Poisons Board will evaluate the applications and issue a permit for medical representatives once the prerequisite conditions have been met. The manufacturer and/or distributor will be responsible for the statements and activities of their medical representatives. Any change of employment by a medical representative must be reported to the Pharmacy and Poisons Board, and a new permit issued with respect to the new employer. All their activities should be carried out in accordance with the code of Promotional Practices for Pharmaceutical Representatives.

Medical representatives should:

- 1.Have an appropriate educational background and should be adequately trained. Employers are responsible for the basic and continuing education of their representatives and should include instruction on appropriate ethical conduct
- 2.Possess sufficient medical and pharmaceutical knowledge and professional integrity to enable them present information on medicines and carry out other promotional activities accurately and responsibly.
- 3.Make available to health care providers complete and unbiased information for each product they promote
- 4.Neither offer inducements to health care providers nor should health care providers solicit such inducements
- 5.Only provide modest quantities (One full dose/cycle) of free samples of legally available prescription medicines to prescribers if requested. The free samples should be labelled "**Physician Sample not for Sale**"
- 6.Not issue free samples of non-prescription medicines for promotional purposes to the general public.

Adverts Withdrawal

In the event a medicine is ordered to be withdrawn from the market in Kenya, it shall remain the responsibility of the market authorisation holders and their locally appointed agents to ensure that any advertisement pertaining to that said product is also terminated and withdrawn from all media with immediate effect.

Penalties

1. The decision of the PPB shall be communicated to the applicant in writing.
2. Any advertiser that fails to comply with these guidelines constitutes an offence and all necessary legal actions as spelt out under the Pharmacy and Poisons Act, CAP 244 section 51, Laws of Kenya, shall be enforced.

Validity

All approved advertisements are valid for one year from date of approval apart from calendars and diaries whose expiries shall be 31st December of the year of granting approval.

The decision of the PPB will be communicated in writing to the applicants.

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.

Appeal

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 PPB. 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.

An appeal shall be lodged within 14 working days of the Board's official communication.

Complaints

The PPB investigates complaints received from anyone who has seen an advertisement for a medicine that in his or her view is misleading or otherwise fails to comply with the legal requirements. To make a complaint, details of when and where the advertisement was seen should be provided, if possible with a copy of the advertisement, together with details of the concerns about the advertisement.

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

Review and Updating of the Guideline

This guideline will be reviewed regularly (every two years or as required) 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.

Annexes

Keeping records

A marketing authorization holder (MAH) also has a duty under the Regulations to keep samples of advertising materials available, to respond to requests for information on advertising materials by providing such items as the PPB may request for consideration and to comply with any decisions taken by the PPB in respect of advertising and promotional material. Failure to do so will be an offence under the Regulations.

The PPB also has powers to require copies of any published advertisement from any person appearing to be involved in its publication, and again failure to comply is an offence. All advertisers must therefore have arrangements to ensure that copies of all advertising material are retained, either by themselves or on their behalf.

To comply with these legal requirements, the PPB considers that the minimum time that materials should be kept for by MAHs and/or other parties is a period of three years after either the last use of the piece or the conclusion of any regulatory or self-regulatory action, whichever is later. Where pieces are likely to be in use by recipients for a period of time, the three years should start from the end of the expected normal period of use.

Companies should consider the need to retain material for a longer time if there are other reasons; particularly if there has been a safety concern or a complaint about advertising of the product.

Requirements for Submitting an Application for Advertisement/ Promotional Material for Medicines.

1. A formal application letter by the Superintending Pharmacist / Pharmacist in Charge of the company, as registered with the Pharmacy and Poisons Board, addressed to “The Registrar, Pharmacy and Poisons Board” detailing the proposed advertisement to be carried out.
2. Proof of up-to-date registration of the company that wishes to advertise with the PPB;
3. Proof of up-to-date registration of the product to be advertised with the PPB;
4. A receipt of the prescribed fee per proposed advertisement, per medium of advertisement, per product advertised towards application. (paid at our Accounts Office)
5. Copy of updated ‘annual practice license’ of the Superintending Pharmacist / Pharmacist in Charge of the company.
6. List of active ingredients (contents) in the medicine to be advertised.
7. If the advertisement is to be:
 - A. Aired on television, in addition to the above:
 1. A detailed story board of the proposed advertisement or one CD copy of the final advertisement proposed to be aired.
 2. Six printed scripts of the messages that will be viewed on TV.
 - B. Aired on radio, in addition to the above:
 1. One CD copy of the proposed advertisement.
 2. Six printed scripts of the messages heard.
 - C. Published in the print media, in addition to the above:
Six printed scripts of the final proposed advertisement.

Note:

- I. All CDs submitted should be CD-R discs.
- II. Documents such as video clips should be viewable via Windows Media Player compatible with Windows 2000 version and thereafter.
- III. Story boards and scripts are viewed by PPB in preparation of the final advertisement.
- IV. The final prepared advertisement will be required to be submitted and necessary approval obtained prior to airing or printing in the respective media.
- V. At no times will approval of the story boards or scripts serve as a substitute to the approval of the final proposed advertisement.

This guideline should be followed at all times for advertisements and promotions unless otherwise justified and approved in an application made to the PPB.

Application Form

PHARMACY AND POISONS BOARD

APPLICATION FOR AUTHORIZATION OF PROPOSED ADVERTISEMENT OR PROMOTION

NAME OF APPLICANT:

PPB REGISTRATION NUMBER:

NAME OF COMPANY PHARMACIST:

REG NO OF COMPANY PHARMACIST:

TICK APPROPRIATELY: ADVERTISEMENT PROMOTION

NAME OF PROPOSED ADVERT/PROMOTION:

PROPOSED MEDIUM OF PROMOTION:

TELEVISION RADIO PRINT MEDIA

OTHER PROVIDE DETAILS):

TYPE OF DOCUMENT SUBMITTED:

FINAL PROPOSED ADVERTISEMENT / PROMOTION

STORY BOARD / SCRIPT FOR REVIEW

OTHER (PROVIDE DETAILS):

	NAME OF PRODUCT TO BE ADVERTISED	PPB REGISTRATION NUMBER	ACTIVE INGREDIENT(S)

PAYMENT DETAILS:

CHEQUE NUMBER.....

DATE OF PAYMENT:

PPB RECEIPT NUMBER:

SIGNATURE OF SUPERINTENDENT PHARMACIST:

COMPANY STAMP:

DATE:

FOR PHARMACY AND POISONS BOARD USE ONLY

APPLICATION NUMBER:

DATE OF RECEIPT OF PROPOSED ADVERTISEMENT / PROMOTION:

.....

REVIEWED IN ADVERTISEMENT COMMITTEE MEETING?

- YES DATE OF MEETING:
- NO REASON:

RECOMMENDATION:

- ACCEPTED AND APPROVED AS IT IS
- CONDITIONAL APPROVAL:
-
- NOT APPROVED:
-

RENEWAL DATE:

RESPONSE LETTER REFERENCE NUMBER:

DATE:

SIGNATURE:



MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Telegram: "MINHEALTH" Nairobi
 Telephone: 020-3562107
 Mobile No. 0733 884 411/0720 608 811
 Fax: 2713409

PHARMACY AND POISONS
 BOARD HOUSE
 LENANA ROAD
 P.O. BOX 27663 - 00506
 NAIROBI

PHARMACEUTICAL REPRESENTATIVE

Personal Detail:

Name: I/D:

PIN no: Address:

Permit Number.....

Qualification..... E-mail.....

Tel No.....

Premises Detail:

Name..... Physical

Address..... Postal Address.....

Employer's Stamp and Sign.....

References:

- I. Ensuring Ethical Promotion of Pharmaceutical Products: Issue Brief- The IFPMA Code, Oct 2009.
- II. Code of promotional Practices for Pharmaceutical Representatives 2006
- III. The Pharmacy and Poisons Act CAP 244 Laws of Kenya
- IV. The Blue Guide Advertising and Promotional of Medicines in the UK.
- V. www.vintagebrowser.com/medicine-ads-1950s/9

Vision:

To be a global leader in the control and regulation of drugs, poisons and the practice of pharmacy.

Mission:

Improving the quality of the life of Kenyans by ensuring the quality, safety and efficacy of pharmaceutical products and service.

**Pharmacy & Poisons Board House
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