DRUG

NATIONAL AUTHORITY

GUIDELINES ON

ADVERTISING AND PROMOTION OF DRUGS IN UGANDA

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Authorization of these guidelines

	Authorized by
Title	Executive Director
Name	
Signature	
Date	25th January 2016

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1.0 PART I

2.0 Background

introduction

National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition). The Act established a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of .

The Vision of NDA: *"A world class drug regulatory agency effectively protecting and promoting public health".*

The Mission of NDA: "*To ensure access to quality, safe and efficacious human and veterinary Drugs and other healthcare products through the regulation and control of their production, importation, distribution and use*".

The National Drug Policy and Authority Act, Sections 2(d) and 5(e) mandate NDA to exercise control on manufacture, production and on the quality of . One of the means of achieving this is through compliance with Good Manufacturing Practice (GMP) requirements as laid down in these guidelines. These guidelines shall therefore be used for GMP inspection of local and foreign manufacturers of medicinal products**.**

The pharmaceutical sector provides a valuable and legitimate contribution to society but it's in the same breath a business whose profitability hinges on marketing and sales. The inherent nature of Drugs to cause harm means that when product sales are given priority, over or poor quality prescribing and poor Drugs use accrue with consequent increase in Drugs adverse effects and higher health-care costs.

Prescribers often find themselves trapped between patients' needs and health-care priorities on the one hand and promotional influences on the other. Dual allegiances and conflicts of interest can cloud judgment and cause distortions in both the delivery of health care and the conduct of research in Drugs.

This guide has been developed to offer guidance to all involved in Drugs promotion on how to conduct their engagements within the realm of legal and ethical provisions of Uganda.

3.0 Interpretation

For the purpose of these guidelines, unless the context otherwise requires:

"**Act**" means the National Drug Policy and Authority Act;

"**Authority**" means the National Drug Authority;

"**Drug**": means any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease or improving physiological functions.

"**Advertisement**" means a notice, circular, label, wrapper and any other promotional material;

"**Drug Promotion**": means the informational and persuasive activities by a manufacturer or distributor the effect of which is to induce the prescription, supply, purchase and/or sale of the drug;

"**Promotional material**" means a written, pictorial or visual material or a verbal statement or reference used in an advertisement;

"**Supplement**": means any article written about or Pharmaceutical companies that is intended to be published in Newspapers or magazines;

4.0 Objectives

The objectives of these guidelines are;

To give guidance on the nature and content of permissible drug promotional materials in Uganda.

To set out the requirements and procedure for application for approval of drug promotional materials.

5.0 Scope

This guideline applies to advertising and promotion of in Uganda.

6.0 Policy

This guide is drawn under section 33(1) and (2), of the National Drug Policy and Authority Act, Cap 206 of the laws of Uganda, and the National Drug Policy and Authority (control of publication and advertisement relating to) regulations No.33 of 2014;

7.0 Distribution

Executive director;

Applicant as defined in section 6(2) of National Drug Policy and Authority (control of publication and advertisement relating to) regulations No.33 of 2014;

NDA website;

A shared folder for all staff on NDA head office server (\\ndaserver\qms\guidelines);

A shared folder for all staff on NDA laboratory server (\\ndqsvr\qms\guidelines);

8.0 PART II

9.0 Requirements for Approval of Promotional Material

9.1 Classification of promotional material

For the purpose of these guidelines, promotional material shall be categorized as follows;

9.1.1 **Category A:** Promotional material that targets prescribers e.g., booklets about a drug, CDs with detailed information about a drug, launches and exhibitions where participation /attendance is limited to health workers or veterinarians, meetings of health and veterinary professionals (for instance, continuing medical education sessions –CMEs). The items take the form of desk calendars, pens, prescription pads etc.

9.1.2 **Category B:** Promotional material that targets medical establishments for instance posters, various visual aids etc.

9.1.3 **Category C:** Promotional material that targets the general public for instance audiovisual messages on over – the – counter (OTC) , posters, bill boards, wall branding and adverts on vehicles, miscellaneous materials like caps, pens, balls umbrellas, and activities like road side shows, talk shows etc.

10.0 Forms of Drug Promotional Materials and Activities Covered in this Guide

The guidelines apply to all promotional material and packaging material submitted with applications for registration of . These may include but not limited to the following material/activity:

10.1 Written material

Written articles or supplements intended to be published in the media, online or any magazine/journal about or pharmaceutical companies.

10.2 Audio/visual messages

Audio and/or visual material appearing on any television or cinema; or distributed to the members of the public; or brought to the notice of the members of the public in any manner whatsoever; which leads to the promotion of the sale of that drug.

10.3 Talk shows

10.4 Visual aids

Posters, packaging designs etc.

10.5 Miscellaneous items

T- Shirts, caps, belts, badges, cutlery, coasters etc.

10.6 Miscellaneous activities

Television programs e.g. news, health talk/entertainment shows, roadside shows, etc.

10.7 Drug promotion symposia, conferences, and other such functions

Materials (e.g., Presentations, audio or video), to be used by participants in these engagements as well as sponsorship of such engagements should be approved by the authority.

10.8 Any other item as the authority may decide

11.0 Categories of Items/ Activities Exempted from this Guide

These guidelines shall not apply to cosmetics, reflexology, acupuncture, and spiritualism. However, if any such adverts should be broadcast/published in these areas, they should not mention diseases listed in the fifth schedule of the NDP/A.

12.0 Application Procedure for Approval of Promotional Material

12.1 Who should apply?

An application for publication or advertisement can be made by:

- the holder of the patent of the drug;
- a licensed person;
- the manufacturer of the drug; or
- an agent authorised by the manufacturer or the holder of the patent of the drug.

12.2 How to apply

All applications for vetting of promotional materials should be made in writing on the Authority's prescribed form (See form 45 of the regulation) and forwarded to the Executive Director of the Authority.

The application should be accompanied by sample(s) of the material for which approval for publication or advertisement is sought (in duplicate); and evidence of payment of the fees prescribed by the authority.

The application form should be signed by the pharmacist in-charge. Where the applying organization does not employ a Pharmacist, the Managing Director shall sign the application form.

12.3 Turnaround time

Upon submission of the application, the applicant shall give the authority 15 working days to communicate a decision pertaining the application. Where the Authority fails to communicate within the 15 working days, it shall notify the applicant in writing stating the reasons for the delay.

12.4 Response to queries

In case of incomplete applications, request for additional information or any other such queries/communications raised about the application, the applicant should respond within 15 working days or furnish an explanation to this effect. Failure to respond within the above stated period, the application will be considered abandoned and shall be archived.

13.0 Requirements for Submitting Applications of Drug Promotional Materials

The applicant should submit promotional material intended for publishing in duplicate.

All samples should be in the ENGLISH Language. For samples that are not in English, the applicant should submit a certified translation of the advert in the English language from Makerere School of languages or any other authority to that language.

13.1 Developing promotional material

The artwork of the promotional material should be vetted and approved before bulk printing. This applies to developing calendars, posters, vehicle branding etc.

All art work/literature should be submitted in the form in which it's intended to be used or in a manner as to represent such a form. E.g. art work for a brochure should be presented as a brochure or bound to represent the final brochure.

The approval for vehicles is specific to a vehicle. Where an approved branding design will be made on more than one vehicle, the applicant should notify the NDA without further payment of vetting fees.

13.2 Requirements for submitting Audio/Visual adverts

The applicant should submit a written script along with the CD / DVDs / tape.

If the advert is in a vernacular language, then a script in both the vernacular and a certified English translation must be submitted before vetting starts.

13.3 Requirements for Importation of drug promotional adverts

Prior to importation of promotional material, the importer should have approval of the promotional material. For promotional material queried at the port of entry, the importer will be summoned to submit a letter of application for vetting.

13.4 Online drug promotion

Applicants intending to engage in online drug promotion should notify the authority on the site(s) they intend to use for these engagements. The authority will carry out surveillance on these sites to ensure that all promotional posts are in conformance with legal provisions.

14.0 PART III

15.0 Content of the Advert

The following should be considered when drafting the content of the advert.

15.1 The drug to be advertised should:

- Not be listed in schedule 1 of the NDP/A Act
- Be legally available in Uganda.

15.2 The advert should:

- Not contravene section 33 (1) and (2) of the NDP/A Act. No advertisement shall mention conditions listed in schedule 5 of the Act.
- Be in agreement with the prevailing national policy on drugs

15.3 Adverts directed or intended for the general public should not contain prescription only Drugs.

15.4 Unsubstantiated claims of superiority over other brands will not be permitted. The information in advertisements should be reliable, accurate, truthful, informative, balanced, up-to-date and capable of substantiation.

15.5 No advertisement for a drug should contain statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such a drug with regard to its safety, quality, or efficacy

15.6 The advertisement should be devoid of misleading unverifiable statements or statements that are exaggerated, unrealistic and misleading.

15.7 Advertisement should have no scenarios to suggest immediate, rushed, quick or abrupt onset of action where it is not so. These could take the form of comparative phrases

15.8 No adverts should contain any reference calculated to lead the public to assume that the product being advertised has some special property / quality which is unknown to or recognized by NDA.

15.9 Advertisements should not contain any statements or visual presentations which directly or by implication, omission, ambiguity, inaccuracy, exaggerated claim, or otherwise, is likely to mislead the consumer.

15.10 Advertisements should not be directed to children, be devised to appeal to them or feature children taking such products. Advertisement should not have any information likely to lead to unsafe practices by children, or other inexperienced persons.

15.11 Where children's pictures are used, they should be illustrational and not promotional. Illustrational pictures may take the form of diagrammatic instructions on the method of administration, the frequency of administration of a product or the age group for which a given product is manufactured.

15.12 Where applicable, appropriate limitations to the use of the Drugs must be pointed out.

15.13 Advertisements should not be so framed as to abuse the trust of the consumer or exploit the consumers' lack of knowledge/experience or their credulity. Consumers should not be led to overestimate the value of Drugs, onset of action, duration of action, effectiveness and underestimate the severity of side effects.

15.14 Advertisements/promotions should not have omissions likely to induce medically unjustifiable drug use or give rise to undue risks.

15.15 Before advertisements are published, advertisers should hold documentary evidence capable of objective substantiation

15.16 Scientific and educational activities should not be deliberately used for promotional purposes.

15.17 Adverts should not be based on endorsements by exaggerated/super human characters.

15.18 Language that brings about fear or distress should not be used.

15.19 Offers of free samples or samples meant for rewarding winners of competitions should be avoided.

15.20 Bonus offers and discounts offered directly to the public are not permissible. The advert can inform the public of the selling price of class C Drugs.

15.21 No advertisement shall contain any offer to diagnose, advise and prescribe.

15.22 No advert should make exaggerated claims through selection of testimonials or other evidence which is not representative of the products effectiveness, by claiming that it possesses some special properties or quality which cannot be established.

15.23 No advertisement should employ any words, phrases or illustrations with curative claims as opposed to the relief of symptoms unless this is how it has been registered and the conditions mentioned are not part of schedule five(annex 1).

16.0 PART IV

17.0 Surveillance of Approved Drug Promotional Materials

17.1 Responsibility of the applicant

The applicant should keep records (except for audio/visual adverts) of the distribution of the approved drug promotional materials in a manner that allows for traceability of the materials and the applicant should on request by the authority furnish such records and any other relevant information.

The applicant should indelibly write or print on every approved drug promotional material, the valid reference number corresponding to the approval of that material before distribution.

Where the applicant doesn't intend to continue using or renew a particular drug promotional material, they should notify the authority to this effect in writing indicating the last approval reference number corresponding to that material.

17.2 Responsibility of the Authority

The authority will carry out post approval surveillance on Drug Promotional Materials in circulation on the market to ensure that no unapproved materials are being used.

The Authority will, in the case of unapproved materials in circulation take administrative and or litigation measures as provided in the regulations to the reprimand the respective marketing authorization holders.

18.0 PART V

19.0 Appendices

19.1 Appendix 1. Fees for vetting drug promotional materials

S.N	Nature of task	Fees in SHS
1.	Screening of Promotional materials per language:	
(a)	written materials	200,000/=
(b)	audio, video and written Scripts	200,000/=
(c)	posters or bill boards on any medium including internet	200,000/=
(d)	Posters on vehicles	200,000/=
(e)	T-shirts	200,000/=
(f)	Miscellaneous Other materials including caps, wall clocks, watches, Umbrellas and bags.	200,000/=

19.1.1 Offences and penalties.

(1) A person contravening a provision of this Act (NDP/A) commits an offence and, where no punishment is provided, is liable—

a) to a fine not exceeding one million shillings;

b) to a withdrawal of the license or permit for a period not exceeding five years;

c) to cause the items in contravention to be impounded, forfeited, destroyed or disposed of in a manner prescribed by the Minister;

d) to imprisonment not exceeding one year; or

e) to any two of the above punishments,

f) and for any subsequent offence under this Act, a person is liable to a fine not exceeding two million shillings or to a term of imprisonment not exceeding five years or to both.

(2) A person who commits an offence under this Act and no other punishment is provided is liable—

a) where the offence relates to class A , to a fine not exceeding two million shillings or to a term of imprisonment not exceeding five years or to both;

b) where the offence relates to narcotic or psychotropic substances under international control and is a second or more subsequent offence, to a term of life imprisonment;

c) where the offence relates to manufacturing, smoking or having possession of any narcotic drug or psychotropic substance under international control and is a second or more subsequent offence, to a term not exceeding ten years.

20.0 Appendix 2. Form 45: Application for Publication or Advertisement for a Drug

1. PARTICULARS OF APPLICANT:

(1) Name of applicant ……..…….....
(2) Physical address/location…….....
(3) Plot No…….....….Street…….....…….City/town……..…..…….....
(4) Box No……..…Telephone no……signature…….....
(5) Full name and title of signatory…….....

2. DESCRIPTION OF PUBLICATION OR ADVERTISEMENT:

(1) Type of activity for which application is made (for example launch, advertisement, talk-show, exhibition)……..…..……
(2) Type of material to be used (for example, posters, literature, bags, calendars) *(applicant to attach 2 samples of materials)*…….....
(3) Drug name …….....
(4) Language of the publication or advert……..…..…….....
(5) Date of submission of application…….....
(6) Intended target group …….....

3. FOR OFFICIAL USE ONLY

(1) Fees payable…….....……..
(2) Receipt No…….....……Date……..... NDA entry No…….....
(3) Application and samples received by (name)…….....
Signature…….Date…….....

21.0 Appendix 3. Fifth Schedule of NDP/A

Diseases as to which publication of descriptive matter is restricted or prohibited.

▪ *Syphilis*	▪ *Gonorrhea*	▪ *Soft chancre*
▪ *Amenorrhea*	▪ *Arteriosclerosis*	▪ *Bladder stones*
▪ *Blindness*	▪ *Nephritis or Bright's Disease*	▪ *Cancer*
▪ *Cataract*	▪ *Deafness*	▪ *Diabetes*
▪ *Diptheria*	▪ *Dropsy*	▪ *Epilepsy or fits*
▪ *Erysipelas*	▪ *Gallstones*	▪ *Glaucoma*
▪ *Goitre*	▪ *Heart disease*	▪ *Hernia or rupture*
▪ *Kidney stones*	▪ *Leprosy*	▪ *Locomotorataxy*
▪ *Lupus*	▪ *Paralysis*	▪ *Pleurisy*
▪ *Pneumonia*	▪ *Poliomyelitis*	▪ *Scarlet fever*
▪ *Schistosomiasis*	▪ *Septicaemia*	▪ *Small pox*
▪ *Tetanus*	▪ *Trachoma*	▪ *Tuberculosis*
▪ *Any form of genitourinary disease*		
▪ *Any structural organic ailment of the auditory system*		
▪ *Other diseases connected with the human and animal reproductive functions*		

22.0 Document Revision History

Date of revision	Revision number	Document Number	Author(s)	Changes made and/or reasons for revision

15/01/2016	0	DAR/GDL/007	Julius Mayengo	This is the first issue of this document