Safe Drugs Save Lives

Guidelines on

Control of Publication and Advertisement Relating to Drugs

National Drug Authority

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Authorization of these guidelines

	Authorized by
Title	Secretary to the Authority
Name	Donna Kusemererwa
Signature	
Date	20th July 2017

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Part 1: Introduction

1.1 The Mandate

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 Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs .

1.2 The Vision

"A Uganda with safe, effective and quality medicines and healthcare products".

1.3 The Mission

"Promoting and protecting public health through the effective regulation of human and animal medicines and health care products".

1.4 The Core Values

- We *care* for the people of Uganda striving for excellence in service to our clients underpinned by professionalism and fairness.
- We take *pride* in what we do, motivated and passionate about achieving the highest standards of service.
- We serve with *integrity* and are honest, transparent and accountable at all times.
- We continuously nurture *team spirit* respecting and supporting each other, working together to achieve our common objectives.
- We take advantage of new opportunities for *learning* and use our knowledge and skills to innovate, creating value for our clients and the public.

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 healthcare and the conduct of research in drugs.

These guidelines are intended to provide a descriptive mechanism to all persons involved in publication, advertising and promotion relating to drugs, on how to conduct their engagements within the realm of legal and ethical provisions in Uganda.

1.5 Objectives of these guidelines

a) To provide descriptive information on the nature and content of permissible drug promotional materials in Uganda.

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

1.6 Scope of these guidelines

These guidelines apply to publication, advertising and promotion relating to drugs in Uganda; and to any other substance, product or service (e.g. cosmetics, reflexology, acupuncture, spiritualism, etc), that mentions or states diseases listed in the fifth schedule of the NDPA Act (see "*Diseases as to which publication of descriptive matter is restricted or prohibited*" in Appendix 1).

These guidelines do not apply to publication of descriptive matter—

a) by direction of the Minister;

b) in a document intended for persons whose profession or employment calls for a knowledge either of drugs generally or of drugs of the description to which the matter in question relates; or

c) for the purposes of an application for the grant of a patent.

1.7 Policy

The National Drug Policy and Authority Act (Cap 206 of the laws of Uganda), Control of publication of descriptive matter, Sections 33(1) and (2) state that:

"(1) Subject to this section, no person shall, by way of advertisement, publish, in whatever manner, in relation to any drug, descriptive matter calculated to lead to the use of that drug—

a) for prevention or treatment of any disease specified in the Fifth Schedule to this Act;
b) for the purpose of termination or influencing the course of human pregnancy; or
c) for any purpose relating to enhancing human potency.

(2) Subject to this section, the authority may, with the approval of the Minister, serve on any person a notice prohibiting him or her from publishing in relation to any drug descriptive matter referred to in the notice."

The Statutory Instrument No.33, The National Drug Policy and Authority (Control of Publication and Advertisement relating to Drugs) Regulations, 2014, Section 4 states that: "*A person shall not make any publication or advertisement for drugs without the approval of the Authority*".

1.8 Distribution

General public on NDA website at www.nda.or.ug

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);

1.9 Interpretation

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

"Act" means the National Drug Policy and Authority Act

"Advertisement" includes any notice, circular, label, wrapper or other document, and any announcement made orally or by means of producing or transmitting light or sound

"Authority" means the National Drug Authority

"Broadcasting" means any means of communication or transmission of information where the recipients of the information cannot be controlled by the sender of the information

"Descriptive matter" means any statement, whether written or oral, which purports to describe the composition or effect of any drug; and references to the publication of descriptive matter shall be references to its publication by way of advertisement, or on or with the container in which the drug is supplied or in any other manner

"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, or for agricultural or industrial purposes

"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;

"Publication" means communication of a message, statement, or text through any means: audio, video, print, electronically as an e-book or on the web.

Part 2: Approval of Advertisement and Publication Material

2.1 Categories of Advertisement and publication materials

Advertisement and publication materials are categorized as follows:

2.1.1 Category A

Material that strictly targets prescribers e.g., printed, engraved or electronic scientific information, including presentations, about a drug or non-scientific information on prescription drugs; 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), symposia, conferences, workshops).

2.1.2 Category B

Material that targets medical or veterinary establishments for instance posters, and various visual aids; which are not necessarily restricted to the respective professionals.

2.1.3 Category C

Material on over-the-counter (OTC) drugs that targets the general public; for instance audio and/or visual messages in broadcast media, posters, bill boards, wall branding and adverts on vehicles, reflector jackets, miscellaneous materials like caps, pens, balls umbrellas, internet and social media.

2.2 Attributes of acceptable Advertisement and publication materials

2.2.1 An advertisement intended for the general public:

a) shall contain information that assists the general public to make rational decisions on the use of the drug;

b) where the advertisement provides information on health issues, it shall not take undue advantage of the concern for health;

c) shall not be for prescription drugs, narcotics or psychotropic drugs, or promote drugs for conditions specified in the Fifth Schedule in Appendix 1.

2.2.2 An advertisement intended for health professionals:

a) shall contain information that is reliable, accurate, truthful, informative, balanced, up-to-date and capable of substantiation;

b) shall where required, indicate the appropriate limitations to the use of the drug;

c) shall not have omissions which are likely to induce medically unjustifiable drug use or give rise to undue risks; and

d) shall not, through selection of testimonials or other evidence which is not representative of the product`s effectiveness, make exaggerated claims or claim that it possesses special properties or quality which cannot be established.

2.3 Application for approval of publications and advertisements for drugs

2.3.1 A person who seeks to make a publication or an advertisement for a drug shall make an application to the Authority in writing on a company letter head and complete and attach a Form 45 (see "*Application for Publication and Advertisement for a Drug",* in Appendix 2).

2.3.2 Prior to production and/or importation, distribution or use of any drug promotional material, or institution of arrangements to engage in any form of drug promotion activity, an application for authorisation to publish or advertise shall be made by:

a) the holder of the patent of the drug;

b) a licensed person;

c) the manufacturer of the drug; or

d) an agent authorised by the manufacturer or the holder of the patent of the drug.

2.3.3 The application shall be accompanied by:

a) A sample of the material for which approval for publication or advertisement is sought. In case of material to be developed, the applicant submits electronic copies of the material artwork showing clearly the final material in its form, colour, dimensions, and inscriptions.

b) Evidence (receipt) of payment of the prescribed fees, issued by NDA (see "*Fees for vetting drug promotional materials"* in Appendix 3).

c) For audio-visual adverts, the applicant is required to submit along with the application, a written script of the advert and the audio/visual files as in the usable format on CD / DVDs / tape or memory stick as samples.

d) If the advert is in any language other than English, then a script in both the language and a certified English translation must be submitted. The translation may be subjected to further scrutiny if the reviewers are not satisfied with it or if it is found to be ambiguous.

2.3.4 Where the terms to be used in an advertisement, are not the recognised scientific terms, the terms shall be consistent with the approved scientific data sheet or other legally determined scientific basis, approved or adopted by the Authority.

2.3.5 Where the language or expressions in the material to be used for publication or advertisement may in the opinion of the Authority cause fear, distress, or

embarrassment or be considered to be out of social order, nature or decency the Authority shall not allow the material to be used.

2.3.6 Where an applicant wishes to amend an application or part of the application submitted to the Authority, the applicant shall pay the prescribed fees for the proposed amendment.

2.3.7 Amendment of materials already authorised by the Authority shall be considered to be a new application for which the applicable fees have to be paid.

2.4 Composition of materials for publications and advertisements

The material for publication or advertisement:

a) should not contravene section 33 (1) and (2) of the NDP/A Act, mention conditions listed in schedule 5 of the Act or 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 the fifth schedule in Appendix;

b) be in agreement with the prevailing National Policy on drugs and authorised treatment guidelines;

c) shall have information that is reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste;

d) shall not contain misleading or unverifiable statements, visual presentations or omissions which directly or by implication, omission, ambiguity, inaccuracy, exaggerated claim, or otherwise, is likely to mislead the consumer, induce medically unjustifiable drug use or which may give rise to undue risks, abuse the trust of the consumer or exploit the consumers' lack of knowledge/experience or their credulity;

e) should not be calculated to make or lead the consumers to overestimate the value of the Drug`s onset of action, duration of action, effectiveness and underestimate the severity of side effects, by depicting scenarios that suggest immediate, rushed, quick or abrupt onset of action where it is not so;

f) shall not contain statements which deviate from, are in conflict with, or go beyond the evidence submitted in the application for registration of such a drug with regard to its safety, quality, or efficacy;

g) should not have statements of comparison with or superiority over other products; these could take the form of comparative claims of efficacy, safety or pricing;

h) shall not refer to products that are not registered in Uganda or products authorized for use under emergency or extraordinary circumstances;

i) shall where required, indicate the appropriate limitations to the use of the drug being advertised or promoted - this may be in respect to the precautions, and indicated dose or dosage or contra indications;

j) shall not have omissions which are likely to induce medically unjustifiable drug use or give rise to undue risks;

k) shall not, through selection of testimonials or other evidence which is not representative of the products effectiveness, make exaggerated claims or claim that it possesses special properties or quality which cannot be established; parading of patients and any form of act likely to violate patients' right to privacy with or without consent will not be acceptable;

l) should not be directed to children, be devised to appeal to them or feature children taking such products; should not have any information likely to lead to unsafe practices by children, or other inexperienced persons, and 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;

m) should not contain any offer to diagnose, advise and prescribe;

n) should not make use of offers of free samples of drugs or samples of drugs meant for rewarding winners of competitions; and

o) should not make bonus offers and discounts directly to the general public.

Part 3: Consideration of an Application by the Drug Authority

Upon receipt of an application for approval of a publication or an advertisement, the Authority shall verify whether the application conforms to the requirements of these guidelines and adopt one of the following dispositions:

3.1 Deferment of the application

Where the Authority is not satisfied with the information provided in the application, the Authority shall direct the applicant to provide further information as may be necessary to complete the application;

3.2 Rejection of the application

Where the Authority does not accept an application, the Authority shall, in writing, inform the applicant of this and the reasons for the decision;

3.3 Approval of the application

Where the Authority is satisfied with an application, the Authority shall approve the application and issue an authorisation to make a publication or an advertisement for a drug, as the case may be; may issue an authorization with conditions.

The authorization shall be issued using Form 46 (see "*Authorisation to make a publication or an advertisement for a drug*" in Appendix 4).

A person who is issued with an authorisation to make a publication or an advertisement relating to a drug, shall not, where conditions are imposed by the Authority, deviate from the conditions or change the authorized publication after approval.

An authorized publication or advertisement shall clearly state that *"the information in this publication/advertisement is approved by National Drug Authority*".

Part 4: Timelines and Responses

4.1 Timelines for vetting of applications

As a regulatory body responsible for protecting the health of the population from harmful effects of drugs, the Authority is committed to providing feedback to the applicant within 15 working days of receipt of the application for vetting of publications and advertising of a drug. Where the Authority fails to communicate within this period, it shall notify the applicant in writing stating the reasons for the delay.

4.2 Response from an Applicant

In case of incomplete applications, request for additional information or any other such queries/communications raised about the application, the applicant shall respond within 15 working days or furnish justification for failure to respond within this period, or else the application will be rejected and the applicant required to re-apply.

Appendices

Appendix 1. Diseases as to which publication of descriptive matter is restricted or prohibited

(Section 33, NDPA Act)

1. Syphilis, gonorrhoea, soft chancre and any form of genitourinary disease or other diseases connected with the human reproductive functions.

2. Any of the following:

Amenorrhoea	Hernia or rupture
Arteriosclerosis	Kidney stones
Bladder stones	Leprosy
Blindness	Locomotorataxy
Brights' disease	Lupus
Cancer	Nephritis or Brights' disease
Cataract	Paralysis
Deafness	Pleurisy
Diabetes	Pneumonia
Diphtheria	Poliomyelitis
Dropsy	Scarlet fever
Epilepsy or fits	Schistosomiasis
Erysipelas	Septicaemia
Gallstones	Smallpox
Glaucoma	Tetanus or lockjaw
Goitre	Trachoma
Heart disease	Tuberculosis or consumption
	Any structural organic ailment of the auditory system

Appendix 2: Application for Publication or Advertisement for a Drug

	National Drug Authority Rumee Tower, Plot No. 19 Lumumba Avenue, P.O. Box 23096, Kampala, Uganda Email: ndaug@nda.or.ug, Tel: +256-414-255665, +256-414-347391, +256-414-347391	**FORM 45**

APPLICATION FOR PUBLICATION OR ADVERTISEMENT FOR A DRUG

The National Drug Policy and Authority (Control of Publication and Advertisement Relating to Drugs) Regulations, 2014; Regulation 6(1)

1. PARTICULARS OF APPLICANT

(1) Name of applicant ……..……..……..……..

(2) Physical address/location……..

(3) Plot No…….Street…….....City/town……..……Country ……...

(4) Box No…….. ……..……Telephone No ……....

(5) Email: ..... Mobile. Tel. No.: .....

(6) Signature……..

(7) 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 product 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) Samples received and assessed by (name)……...

Signature……..Date……..

Appendix 3: Fees for vetting drug promotional materials

Sr. No.	Nature of task	Fees in UGX
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/=

Appendix 4: Authorisation to make a publication or an advertisement for a drug

Safe Drugs Save Lives	**National Drug Authority** Rumee Tower, Plot No. 19 Lumumba Avenue, P.O. Box 23096, Kampala, Uganda Email: ndaug@nda.or.ug, Tel: +256-414-255665, +256-414-347391, +256-414-347391	**FORM 46**

AUTHORISATION TO MAKE A PUBLICATION OR AN ADVERTISEMENT FOR A DRUG

The National Drug Policy and Authority (Control of Publication and Advertisement Relating to Drugs) Regulations, 2014; Regulation 7(6)

This is to certify that ……. , is authorised to make a publication or an advertisement for the following drugs:

1 …….....
2 …….....
3 …….....
4 …….....
5 …….....
6 …….....
7 …….....

This authorisation is issued with the following conditions:

1 …….....
2 …….....
3 …….....
4 …….....
5 ...…….....

This authorization is valid from ……..... .. to …….....

……

For: NATIONAL DRUG AUTHORITY.

Date of issuance:……..

References

Francer et al. 2014. *Ethical pharmaceutical promotion and communications worldwide*: *codes and regulations.* Philosophy, Ethics, and Humanities in Medicine 2014, 9:7

Norris P, Herxheimer A, Lexchin J & Mansfield P (2005). *Drug promotion: What we know, what we have yet to learn.* World Health Organization and Health Action International, Geneva.

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