STATUTORY INSTRUMENTS
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STATUTORY INSTRUMENTS SUPPLEMENT

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S T A T U T O R Y I N S T R U M E N T S

2014 No. 33.

THE NATIONAL DRUG POLICY AND AUTHORITY (CONTROL OF PUBLICATION AND ADVERTISEMENT RELATING TO DRUGS) REGULATIONS, 2014.

ARRANGEMENT OF REGULATIONS

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SCHEDULE

S T A T U T O R Y I N S T R U M E N T S

2014 No. 33.

The National Drug Policy and Authority (Control of Publication and Advertisement Relating to Drugs) Regulations, 2014.

(Made under Sections 33 and 64 of the National Drug Policy and Authority Act, Cap 206)

IN EXERCISE of the powers conferred upon the Minister responsible for health by sections 33 and 64 of the National Drug Policy and Authority Act and on the advice of the National Drug Authority, these Regulations are made this 24th day of March, 2014.

1. Title.
These Regulations may be cited as the National Drug Policy and Authority (Control of Publication and Advertisement Relating to Drugs) Regulations, 2014.

2. Interpretation.
In these Regulations, unless the context otherwise requires—

"Act" means the National Drug Authority Act;

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

"promotional material" means a written, pictorial or visual material or a verbal statement or reference used in an advertisement.

3. Application.
These Regulations apply to all activities and materials for publications related to drugs or advertisements for drugs including promotions, promotion materials and packaging materials.

4. Approval of publications and advertisements.
A person shall not make any publication or advertisement for drugs without the approval of the Authority.

5. Composition of materials for publications and advertisements. The material for publication or advertisement—

(a) shall be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste; and

(b) shall not contain misleading or unverifiable statements or omissions which may induce medically unjustifiable drug use or which may give rise to undue risks.

6. Application for approval of publications and advertisements for drugs.

(1) A person who seeks to make a publication or an advertisement for a drug shall make an application to the Authority, using Form 45 in the Schedule to these Regulations.

(2) An application for publication or advertisement 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.

(3) The application shall be accompanied by—

(a) a sample of the material for which approval for publication or advertisement is sought; and

(b) the prescribed fees.

(4) Where the language of the materials required under subregulation (3) is not English, the materials shall be presented with certified English translations.

(5) 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.

(6) Where the language to be used for publication or advertisement may in the opinion of the Authority cause fear or distress, the Authority shall not allow the material to be used.

(7) 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.

7. Consideration of application by the Authority.

(1) Upon receipt of an application for approval of a publication or an advertisement made under regulation 6, the Authority shall verify whether the application conforms to the requirements of these Regulations.

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

(4) 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.

(5) The Authority may issue an authrorisation with conditions.

(6) The authorisation shall be issued using Form 46 in the Schedule.

(7) A person who is issued with an authorisation to make a publication or an advertisement for a drug, shall not, where conditions are imposed by the Authority, deviate from the conditions.

8. Advertising of drugs using approved materials.

(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, shall not take undue advantage of the concern for health; or

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

(2) An advertisement intended for pharmacists and other 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 products effectiveness, make exaggerated claims or claim that it possesses special properties or quality which cannot be established.

9. Offences and penalties.

A person who contravenes a provision of these Regulations commits an offence and is on conviction liable to a penalty in the Act.

SCHEDULE

Regulation 6(1)

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…….

Regulation 7 (6)

Form 46

AUTHORISATION TO MAKE A PUBLICATION OR AN ADVERTISEMENT FOR A DRUG

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 issue with the following conditions –

1 ……
2 ……
3 ……
4 ……
5 ...……..

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

……
For: NATIONAL DRUG AUTHORITY.

Date of issuance:……..

RUHAKANA RUGUNDA (DR.)
Minister of Health.