3. Declaration by the offender

I/ We.....do hereby admit to have committed the offence specified under the paragraph (2) of this schedule, hence without undue influence, commit ourselves that we are voluntarily willing and accept to pay fine of TZS.....and that, unless by order of the court, no further criminal or as the case may be, civil proceedings shall be taken against ourselves in respect of this offence to which power to compound offence has been exercised.

Full Name.....
Signature.....
Dated at .....this.....day of.....201....

4.Payment (For official use only)

Amount of fine to be paid.....
Name and signature of Authorized officer.....
Name and signature of cashier.....
Receipt number.....
Date and stamp.....
NB: Cashier should attach copy of receipt

Dar-es-Salaam,
29th March, 2010

DAVID H. MWAKYUSA (MP.),
Minister for Health and Social Welfare

GOVERNMENT NOTICE NO. 160 published on 23/4/2010

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT

(CAP. 219)

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THE TANZANIA FOOD, DRUGS AND COSMETICS ACT (CAP. 219)

REGULATIONS

(Made under Section 95 and 122(1) (r))

THE TANZANIA FOOD, DRUGS AND COSMETICS (CONTROL OF DRUGS AND HERBAL DRUGS PROMOTION) REGULATIONS, 2010

PART I
PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Control of Drugs and Herbal Drugs Promotion) Regulations, 2010.

Application

2. These Regulations shall apply in Mainland Tanzania.

Interpretation

3. In these Regulations, unless the context otherwise requires-

Cap 219

"Act" means the Tanzania Food, Drugs and Cosmetics Act;

"advertisement" means and includes every form of advertising, whether in a publication, or by the display of any notice or by means of any catalogue, price list, letter, whether circular or addressed to a particular person or by the exhibition of a photograph or a cinematograph film, or by way of sound recording, sound broadcasting, or television or any other means of communication;

"Authority" means the Tanzania Food and Drugs Authority or the acronym "TFDA" established by section 4 of the Act;

"dispense" means the supply of a drug, or herbal drug and in accordance with a prescription lawfully given by a medical practitioner, dentist or veterinary surgeon;

"drug", means any substance or mixture of substances manufactured, sold or presented for use in-

(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;

(d) articles intended for use as a component of any articles specified in clause (a), (b) or (c); but does not include medical devices or their components, parts or accessories;

"drug promotion" has the same meaning as provided under Regulation 4 to these Regulations.

"General public" means persons 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" 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 incase of veterinary drugs it includes veterinary surgeons and veterinary paraprofessionals;

"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;

"International Drug Control Convention" includes-

(a) the Single Convention on Narcotic Drugs, 1961, adopted by the United Nations Conference at New York in March, 1961;

(b) the Protocol, amending the Convention mentioned in sub-clause a), adopted by the United Nations Conference at Geneva in March, 1972;

(c) the Convention on Psychotropic Substances, 1971, adopted by the United Nations Conference at Vienna on 1st February, 1971;

(d) United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted at Vienna on 19th December, 1988; and

(e) any other international drug control convention, or protocol or other instrument amending an International Drug Convention, relating to narcotic drugs, precursor chemicals or psychotropic substances which may be ratified or acceded to by the United Republic after the commencement of this Act;

"manufacturer" means a 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 who possesses the qualifications ascribed under regulation 19 to these Regulations;

"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 these Regulations means a drug or herbal drug;

"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;

"reminder advertisement" means advertisement that is designed to remind a healthcare worker and general public of a product's existence but do not contain promotional claims.

PART II
PROMOTION

Elements of drug promotion

4.-(1) Any activity undertaken in the manner provided hereunder shall constitute drug promotion:

(a) Advertising;

(b) the activities of representatives including detail aids and other printed material used by representatives;
(c) the supply of samples;
(d) the provision of inducements to prescribe, dispense, supply, administer, recommend or buy products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
(e) the provision of hospitality for promotional purposes;
(f) the sponsorship of promotional meetings;
(g) the sponsorship of scientific meetings including payment of travelling and accommodation expenses in connection therewith;
(h) the provision of information to the general public either directly or indirectly;
(i) 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) The following activities shall not form drug promotion-
(a) replies made in response to individual enquiries from healthcare workers or employees in response of specific communications from them whether of enquiry or comment;
(b) letters published in professional journals, if they relate solely to the subject matter of the letter or enquiry, are accurate, not misleading not promotional in nature.
(c) factual, accurate, informative announcements and reference material concerning licensed medicines relating, to pack changes, adverse reaction warnings, trade catalogues and price lists, provided they include no product claims;
(d) summaries of product characteristics;
(e) the labelling on medicines and accompanying package leaflets, Provided they are not promotional for the products concerned; and
(f) statements relating to human health or diseases provided there is no reference, either direct or indirect, to specific products.

Criteria for product to be promoted

5.-(1) No product shall be promoted unless it is registered by the Authority.

(2) All packaging and labelling materials shall provide information which is consistent with that approved during the registration of the product.

(3) 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.

Content of promotional materials

6. The content of promotional materials must be unbiased, accurate, informative, up to date, in good taste 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 likely to induce medically unjustifiable product use or to give rise to undue risks.

Restrictions on advertisement

7.-(1) A person shall not conduct an advertisement of a drug unless he applies and be issued with a written approval from the Authority.

(2) A person shall not use any promotional material to advertise any product unless he applies and be issued with a written approval from the Authority as per paragraph (4) of Regulation 7.

(3) An advertisement to the general public shall not refer to the Act, the Authority or any employee of the Authority.

(4) Every application for a permit to use a promotional material shall be made to the Authority by submitting a dully filled in Application Form for Approval of Promotional Materials as set out in the First Schedule to these Regulations.

(5) Every application for a Trade Fair Permit shall be made to the Authority by submitting a dully filled Application Form For Trade Fair Permit as set out in the Second Schedule to these Regulations and be accompanied by fees as prescribed in the Tanzania Food, Drugs and Cosmetics (Fees and Charges) Regulations, 2005.

GN. No. 439 of 2005

(6) Every application for a permit to use promotional material shall be accompanied by fees as prescribed in the Tanzania Food Drugs and Cosmetics (Fees and Charges) Regulations, 2005. GN. No. 439 of 2005

(7) The Authority shall, if satisfied that the proposed promotional material complies with the requirements prescribed in these Regulations, issue a permit for Advertisement as set out in the Third Schedule to these Regulations with such conditions as it may consider necessary;

(8) Companies shall preserve permits for promotional material and the relevant materials for not less than two years after the final use, or the date of the meeting and produce them on request from the Authority.

(9) Companies shall preserve permits for promotional material and the relevant materials in the form certified for not less than two years after the final use of the promotional material or the date of the meeting and produce them on request from the Authority.

Advertisement to health care workers

8.-(1) 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;
(b) the name of the active ingredient using either International nonproprietary names or the generic name of the drug;
(c) content of active ingredient per dosage form or regimen;
(d) name of other ingredients known to cause problems;
(e) approved therapeutic uses;
(f) dosage form or regimen;
(g) side-effects and major adverse effects;
(h) precautions, contra-indications and warnings;
(i) major interactions;
(j) name and address of manufacturer; and
(k) reference to scientific literature as appropriate

(2) Any Advertisement which use words such as "number one product", "the best product" or any other such words in promoting a product are hereby prohibited.

Comparison of Products

9.-(1) Comparison of products for competition purposes is prohibited;

(2) Comparison of products should not be disparaging, it shall be factual, fair, reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way;

(3) "Hanging" comparatives; those which merely claim that a product is better, stronger, more widely prescribed is prohibited.

Advertisement to the general public

10. Advertisement targeted to the general public shall contain the following-

(a) the generic name of a drug, brand name of the drug;

(b) name of the active ingredient using International non proprietary names;

(c) approved major indication for use;

(d) major precautions, contra-indications and warnings;

(e) name and address of manufacturer;

(f) dosage regimen; and

(g) phrase "maumivu yakizidi muone daktari" or "If symptoms persist, seek medical advice."

(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; and

(c) Not take undue advantage of people's concern for their health.

Reminder advertisement

11.-(1) Reminder advertisements shall include the generic name, brand name, the international nonproprietary name or the name of each active ingredient, and the name and address of the manufacturer and must not contain promotional claims.

(2) A person shall not promote any drug product in a manner that is false, misleading, or deceptive or is likely to create erroneous impression regarding its character, value, quantity, composition, merit or safety as the case may be.

Restrictions on advertising to the general public

12.-(1) Product advertisement material shall not contain pictures of internal or sexual organs in advertisements to the general public.

(2) A person shall not advertise to the general public any drug other than general sales and pharmacy only drugs.

(3) Any language that brings or is likely to mislead or deceive or create fear or distress to individuals or community is prohibited.

(4) Any product advertisement which may induce or attract children to use any product.

PART III
SAMPLES FOR PROMOTIONAL PURPOSE

Provision of Free samples

13.-(1) Sell or supply of free samples of the product to the general public for a promotional purpose is hereby prohibited.

(2) Samples of products shall be provided only to a medical practitioner, dentist, veterinary surgeons or pharmacist for products which they are entitled to prescribe or dispense.

(3) Medical representative who distribute samples shall keep proper records of those who have been given the samples.

(4) Product samples must be well and clearly labeled or marked "Free Samples – Not For Sale" and must be accompanied by a copy of the approved summary of product characteristics.

(5) Free samples of product must be the smallest pack size registered by the Authority.

Restriction on provision of sample

14. The provision of samples shall not apply to-

(a) any drug which contains a substance listed in any of schedules I, II or IV to the Narcotic Drugs Convention where the medicine is not a preparation listed in Schedule III to that Convention; or

(b) a substance listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the medicine is not a preparation which may be exempted from measures of control in accordance with paragraphs 2 and 3 of article 3 to that convention.

Provision of gift, inducement and other benefits

15.-(1) No gift, benefit in kind or pecuniary advantage shall be offered or given to healthcare workers, their families or employees as an inducement to prescribe, supply, administer, recommend or buy any product.

(2) No gift in the form of promotional aids and prizes whether related to a particular product or of general utility shall be distributed to healthcare workers unless the gift or prize is reasonably inexpensive and relevant to the practice of their profession or employment.

PART IV

SYMPOSIA AND OTHER MEETINGS

Approval for conducting Symposia and other meetings

16.-(1) No product promotional meeting or any other meetings or gathering where a drug or herbal drug may be promoted without the approval of the Authority.

(2) Any person wishing to conduct such meetings shall submit to the Authority an application in a prescribed form as provided under Second Schedule to these Regulations and shall be accompanied with a prescribed fee.

(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.

Sponsors of scientific symposia or meeting

17. Sponsorship of any scientific symposia or meeting or support to individual healthcare workers to participate in any symposia or meeting shall not be conditional to promote any particular product.

PART V
MEDICAL REPRESENTATIVES

Application for Medical representatives permit

18.-(1) A person wishing to practice as a Medical Representative shall submit to the Authority a dully filled application for a Medical Representative Permit as set out in the Fourth Schedule to these Regulations accompanied by a fee prescribed under the Fees and Charges Regulations, 2005.

GN. No. 439/2005

(2) The Authority shall, if satisfied, issue a written Medical Representative Permit as set out in the Fifth Schedule to these Regulations with such conditions as it may consider necessary.

Qualification of a Medical Representative

19. A Medical Representative shall possess a minimum qualification of a diploma in medical, pharmaceutical, veterinary or biological sciences or chemistry from recognized institution.

Obligation of a Medical Representative and Product registrant

20. A Medical Representative shall not, when promoting products, make available to prescribers or dispensers complete and unbiased information relating to the product.

(2) A Medical Representative shall not make claims or comparisons, which are-

(a) inaccurate, misleading, disparaging;

(b) inconsistent with information contained in the approved Summary of Product Characteristics.

(3) A Medical Representative shall report to the Authority all the information relating to the safety of product received from healthcare workers.

(4) Product registrants or employer shall be responsible for the statements and activities of their Medical Representatives.

PART VI
OFFENCES AND PENALTIES

Penalty

21. Any person who contravenes any provision of these Regulations commits an offence and upon conviction is liable to-

(a) if such a person is an individual, a fine of not less than one hundred thousands shillings or to imprisonment for a term not less than two weeks or to both such fine and imprisonment;

(b) if such a person is a body corporate or association, to a fine of not less than one million shillings.

Compounding of offences

22.-(1) Notwithstanding the provisions of Regulation 21, the Director General or the Drug Inspector authorized to act on his behalf may, if circumstances show that a person, corporate or unincorporated body has committed any offence against these Regulations in respect to which he has showed willingness to pay a fine, compound such offence by accepting the fine in respect of which the offence has been committed.

(2) Without prejudice to provisions of sub-regulation (1), the Director General or an Inspector authorized to act on his behalf before accepting a fine require such a person to fill in a Compounding Form as provided in the Sixth Schedule to these Regulations.

(3) Subject to the provisions of these Regulations authorizing any measures that may be taken pursuant to an order of the court, no further criminal proceedings shall be taken against a person in respect of whom a power to compound offence has been exercised.

PART VII
GENERAL PROVISION

Revocation of G.N.No. 440 of 1999

23. The Pharmaceuticals and Poisons (Code of Conduct for Drug Promoters) Notice, 1999 is hereby revoked.

FIRST SCHEDULE

(Made under regulation 7(4))

TFDA FORM NO.....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

Tanzania Food & Drugs Authority

APPLICATION FORM FOR APPROVAL OF PROMOTIONAL MATERIALS

NB: Giving false or misleading information is an offence

(All information supplied in this form must be either typed or written in block capital letters)

Applicant Particulars

Name of applicant:.....

Address: .....

.....

Contact person: ..... **E-mail:**.....

Telephone Number: ..... **Fax Number:** .....

Sponsor Particulars (if different from the applicant)

Name of Sponsor:.....

Address: .....

.....

Contact person: ..... **E-mail:**.....

Telephone Number: ..... **Facsimile Number:** .....

Product Particulars

Product type (please tick the appropriate box)

Prescription Only Medicine [ ] Pharmacy Only Medicine [ ]

General Sales Medicine [ ] Controlled Medicine [ ]

Product Name/s .....

Registration number.....

Name of registration holder.....

Active ingredient(s) and strengths of the product

1. .....
2. .....
3. .....
4. .....

Type of material: (please tick the appropriate box)

Poster [ ] Leaflet [ ] Cinema [ ] Outdoor/Billboard [ ] In/On Public Transport[ ]

Magazines/Newspaper[ ] Literature [ ] Radio [ ] Television[ ]

Other [ ] please specify .....

This form shall be accompanied by:

NB: Please tick or mark X on Checklist

[ ] A copy of the proposed advert (Script, Sketch, Audio tape, CD, VCD, Video cassette.)
[ ] Current indications of use as indicated on Certificate of Registration (where applicable).
[ ] Copy of any research/surveys/data mentioned in advertisement
(Note – further evidence to be provided if requested).
[ ] Copy of previous approval (If the advert is a reminder)
[ ] Copy of approval for the use of a restricted/prohibited claim (if applicable).
[ ] Application fee.

Applicant declaration

I, ...declare that the information contained within this application is true and correct.

Signed: ..... Date :.....

FOR OFFICIAL USE ONLY

Fees Tshs..... Receipt No..... of .....

Permit granted/not granted

because.....

.....

Permit No..... Approved by ..... of .....

....

Date Director General

SECOND SCHEDULE

(Made under regulation 7(5))

TFDA FORM NO. ....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

Tanzania Food & Drugs Authority

APPLICATION FORM FOR TRADE FAIR PERMIT

(All information supplied in this form must be either typed or written in block capital letters)

Applicant Particulars

Name of applicant: .....

Address: .....

.....

Contact person: ..... **E-mail:** .....

Telephone Number: ..... **Fax Number:** .....

Sponsor Particulars (if different from the applicant)

Name of Sponsor: .....

Address: .....

.....

Contact person: ..... **E-mail:** .....

Telephone Number: ..... **Facsimile Number:** .....

Government Notice No. 160 (contd.)

Products Particulars

S/N	Name of product	Registered?		Registration number	Type of Material
		Yes	No		

(Add as many rows as you can)

Note: Type of materials includes: Poster, Leaflet, Cinema, Billboard, Literature, Sample of products etc.

This promotion will take place at ..... (mention place) for a duration of.....

This form shall be accompanied by:

NB: Please tick or mark X on items below:

[ ] A copy of adverts (script, audio tape, CD, Video cassette)
[ ] Application fee.

Applicant Declaration

I, ...declare that the information contained within this application is true and correct.

Signed: ..... Date :.....

NB: Giving false or misleading information is an offence

FOR OFFICIAL USE ONLY

Fees ..... Receipt No..... of .....

Permit granted/not granted because.....

.....

Permit No..... .....of .....

Date..... Director General .....

THIRD SCHEDULE

Made under regulation 7(7))

TFDA FORM NO. ....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

Tanzania Food & Drugs Authority

PERMIT FOR ADVERTISEMENT

Permit No.....

Permit is hereby granted to M/S.....for advertisement of ..... through ..... subject to the maintenance of records such as required by the law and it shall not be transferable.

The validity of this permit expires on:.....

Granted by Tanzania Food and Drugs Authority this.....day of.....20.....

.....

DIRECTOR GENERAL

FOURTH SCHEDULE

(Made under regulation 18(1))

TFDA FORM NO. ....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

Tanzania Food & Drugs Authority

APPLICATION FOR MEDICAL REPRESENTATIVE PERMIT

(All information supplied in this form must be either typed or written in block capital letters)

I/We.....

of postal address.....

being engaged in the sale and supply of pharmaceuticals, hereby make an application that my/our representative, Dr./Mr./Mrs/Ms .....be permitted to possess pharmaceuticals as scheduled below, for the purpose of giving free samples to persons who may lawfully posses such pharmaceuticals.

His qualification(s) [Medical representative] is/are.....

I/We enclose the following authenticated copies of his certificates:-

.....

.....

.....

.....

NB: Giving false or misleading information is an offence

Signature..... **Date** .....

(Applicant)

Signature ..... **Date** .....

(Medical Representative)

FIFTH SCHEDULE

(Made under regulation 18(2))

TFDA FORM NO. ....

THE TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

Tanzania Food & Drugs Authority

MEDICAL REPRESENTATIVE PERMIT

Permit No. .....

Dr./Mr./Mrs./Ms.....being a Medical Representative of .....is hereby permitted to posses and supply free samples of pharmaceuticals to a person who may lawfully possess such pharmaceuticals subject to the maintenance of records as required by the law.

This permit shall not be transferable.

The validity of this permit expires on:.....

Granted by Tanzania Food and Drugs Authority this.....day of..... .....20.....

.....

DIRECTOR GENERAL

SIXTH SCHEDULE

[Made under regulation 21(3)

TFDA FORM No. .....

TANZANIA FOOD AND DRUGS AUTHORITY

TFDA

Tanzania Food & Drugs Authority

COMPOUNDING OF OFFENCES FORM

(For official

(Print, type or write in capital letters)

1. Particulars of the person/offender

Name of the person/Company.....

Postal address:.....

Street/Rd ..... Plot/House Number.....

Contact person: ..... E-mail:.....

Telephone Number: ..... Fax Number: .....

2. Type of the offence and the penalty

1. Offence: .....

2. Penalty:.....

3. The following products equipments used to commit the offence or were seized.

5.....	8.....
6.....	9.....
7.....	10.....
8.....	11.....
9.....	12.....
10.....	13.....
.....	14.....

3. Declaration by the offender

I/ We.....do hereby admit to have committed the offence specified under the paragraph (2) of this schedule, hence without undue influence, commit ourselves that we are voluntarily willing and accept to pay fine of TZS.....and that, unless by order of the court, no further criminal or as the case may be, civil proceedings shall be taken against ourselves in respect of this offence to which power to compound offence has been exercised.

Full Name.....

Signature.....

Dated at.....this.....day of.....20.....

4. Payment (For official use only)

Amount of fine to be paid.....

Name and signature of Authorized officer.....

Name and signature of cashier.....

Receipt number.....

Date and stamp.....

NB: Cashier should attach copy of receipt

Dar es Salaam,
29th March, 2010

DAVID H. MWAKYUSA,
Minister for Health and Social Welfare

GOVERNMENT NOTICE NO. 161 published on 23/4/2010

THE TANZANIA FOOD, DRUGS AND COSMETICS ACT
(CAP. 219)

REGULATIONS

ARRANGEMENT OF REGULATIONS

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PART III
LABELING

PART IV
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