GOVERNMENT NOTICE NO. …… published on ……

THE TANZANIA MEDICINES AND MEDICAL DEVICES ACT
(CAP. 219)

REGULATIONS

(Made under sections 95 and 122(1) (p))

THE TANZANIA MEDICINES AND MEDICAL DEVICES (CONTROL OF HUMAN AND VETERINARY MEDICINES PROMOTION) REGULATIONS, 2022

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ARRANGEMENT OF REGULATIONS

SCHEDULES

	PART I PRELIMINARY PROVISIONS
Citation	**1.** These Regulations may be cited as the Tanzania Medicines and Medical Devices (Control of Human and Veterinary Medicines Promotion) Regulations, 2025 and shall come into force after publication in the official Government Gazette
Scope and application	**2.** These Regulations shall apply to human and veterinary medicines including biological products, biocidal products and herbal medicines; and excludes traditional medicines, intended to be promoted in Mainland Tanzania.
Interpretation	**3.** In these Regulations unless the context otherwise requires-
	"abbreviated advert" means a reminder advertisement which contains company name, company logo or product name;
Cap. 219	"Act" means the Tanzania Medicines and Medical Devices Act;
	"advertisement" means a form of advertising, whether in a publication, or by display of any notice or by means of any catalogue, price list, letter, whether circular or addressed to a particular group of persons 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; including social media, electronic communications, verbal advertisement or anything spoken in public;
	"Authority" means the Tanzania Medicines and Medical Devices Authority established under section 4 of the Act, which is also known by its acronym as "TMDA";
	"biocidal product" means preparation containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. For the purpose of these regulations, it shall include antiseptic and disinfectant products;
	"biological product" means medicines which are grown and then purified from large-scale cell cultures of bacteria or yeast, or plant or animal cells including vaccines, growth factors, immune modulators, monoclonal antibodies, as well as products derived from blood and plasma;
	"comparative claim" means a claim that compares two or more medicinal products in terms of economical merits, performances, safety or quality;
	''dispense'' means the supply of medicines with or without a prescription lawfully given by a medical practitioner, dentist or veterinarian;
	"general public" means persons other than healthcare workers;
	"general sale medicines" means any medicine whose use does not need the direction or prescription by a medical practitioner, dentist or

	veterinarian;
	"healthcare workers" means members of the medical, dental, pharmacy, laboratory technology and nursing professions and any other person who in the course of their professional duties may prescribe, supply or administer a human medicine and incase of veterinary medicines it includes veterinarians and paraprofessionals;
	"herbal medicines" means finished medicinal products which contain one or more standardised active ingredients of natural origin derived from plants and excludes traditional medicines;
	"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 medicines;
	"medical claim" includes any statement that conveys information about a disease state or the attributes of a medicinal product in respect of its therapeutic use;
	"medicines", 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 function in man or animal; or
	(c) disinfection in premises in which medicines 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;
	"medicines promotion**"** means any informational and persuasive activity undertaken by a pharmaceutical company or with its authority which promotes the prescription, supply, sale or administration of its product;
	‘‘prescription medicine" means any product required to be dispensed only upon a prescription given by a medical practitioner, dentist or veterinarian or any other person approved by the relevant professional bodies;
	"products" means human, veterinary, or herbal medicines and antiseptics or disinfectants;
	"promotional material" means any representation concerning the attributes of a product conveyed by any means for the purpose of persuading 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; and

	"traditional medicines" means and includes any methods, processes, practices or any medicine consisting of a substance or mixture of substances produced by drying, extracting, crushing, comminuting or compressing natural substances of plants or mineral origin or any part of such substances.

	PART II PROMOTION AND ADVERTISEMENT CONTROL
Medicines promotion	**4.**-(1) Any activity undertaken in the manner provided hereunder shall constitute medicines 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 as a 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; and
	(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) Notwithstanding the provisions of subregulation (1), the following shall not be considered as medicines promotional activities-
	(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;
	(b) factual, accurate, informative announcements and reference material concerning registered medicines and relating, for example, to pack changes, adverse reaction warnings, trade catalogues and price lists, provided they include no product claims;
	(c) summaries of product characteristics;
	(d) the labelling on medicines and accompanying package

	leaflets insofar as they are not promotional for the products concerned; and
	(e) statements relating to human health or diseases provided there is no reference, either direct or indirect, to specific products.
Restrictions on product promotion	**5.**-(1) A product shall not 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) A product shall not 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.
	(4) Product advertisement material shall not contain pictures of internal or sexual organs in advertisements to the general public.
	(5) Any language that brings or is likely to mislead or deceive or create fear or distress individuals or community is prohibited.
	(6) Any product advertisement which may induce or attract children to use any product is prohibited.
	(7) An advertisement to the general public shall not refer to the Act, any department, or official of the Authority, government logo or symbol.
	(8) Promotion and advertisement of products in open marts and public means of transport is hereby prohibited under these Regulations.
Content of promotional materials	**6.**-(1) The content of promotional materials must be unbiased, accurate, informative, up to date, not misleading and consistent with information approved during registration of the product.
	(2) Promotional materials 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) Promotional materials shall be in English, Kiswahili or both languages.
Application for approval of promotional materials and activities	**7.**-(1) An application for advertisement of a medicine shall be made by an applicant and shall be accompanied by the following- (a) a dully filled form prescribed in the First Schedule of these Regulations; (b) a copy of the proposed advert; and (c) a non-refundable application fee as prescribed in the Fees and Charges Regulations in force.
	(2) Subject to subregulation (1)(c), application fees shall be

	charged per promotional material.
	(3) The Authority shall review the application for advertisement of a medicine in accordance to the guidelines issued from time to time.
	(4) After review of an application for advertisement of a medicine, the Authority may issue a permit as prescribed in the Second Schedule of these Regulations.
	(5) Subject to subregulation (4), the permit for advertisement of medicines shall be valid for a period of 2 years.
Renewal of approved promotional material	**8.**-(1) An application for renewal of advertisement of a medicine shall be made 30 days before the validity of the permit issued under regulation 7 (4).
	(2) Subject to subregulation (1), an application for renewal of advertisement of a medicine shall be made by an applicant and shall be accompanied by the following- (a) a dully filled form prescribed in the First Schedule of these Regulations; (b) a copy of the proposed advert; and (c) a non-refundable application fee as prescribed in the Fees and Charges Regulations in force.
Variations	**9.**- (1) All variations of an approved advert shall be notified to the Authority and implemented upon approval issued by the Authority.
	(2) Notwithstanding subregulation (1), variations that involve change or addition of the message in the advert shall be considered as a new advert and the same shall require a new application.
Advertisement to health care workers	**10.** 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(s) of the active ingredient(s) using either international non-proprietary names (INN) or the generic name of the medicine;
	(c) content of active ingredient(s) 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; or
	(k) reference to scientific literature as appropriate.

Advertisement of scheduled medicines GN No. 63	**11.** -(1) Controlled drugs, prescription only and pharmacy only medicines as prescribed in Scheduling of Medicines Regulations shall not be advertised to the general public.
	(2) Notwithstanding subregulation (1), prescription only and pharmacy only medicines may be advertised to healthcare workers.
	(3) Over the counter and general sale medicines may be advertised to the general public and healthcare workers.
	(4) The Authority may authorise advertisement of prescription only medicines to the general public for the public interest.
Comparison of products	**12.** -(1) Comparison of products for competition purposes is prohibited.
	(2) Comparison of products for non-competing purposes may be allowed but shall not be disparaging, must be factual, fair, reflecting the body of evidence and shall not mislead by distortion, undue emphasis or in any other way.
	(3) "Hanging" comparatives; which merely claim that a product is better, stronger, superior, more widely prescribed, or any other such claims are prohibited.
Advertisement to the general public	**13.** - (1) Advertisement targeted to the general public may contain the following-
	(a) the generic name of a medicine, brand name of the medicine;
	(b) name(s) of the active ingredient(s) using international non-proprietary names;
	(c) approved major indications 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 the public to make an informed decision on the choice and use of medicines determined to be legally available without a prescription;
	(b) take account of the public legitimate desire for information regarding their health; and
	(c) not take undue advantage of public's concern for their health.
Reminder advertisements	**14.** Reminder advertisements shall include at least the generic name, brand name, the international non-proprietary name or the name of each active ingredient, and the name and address of the manufacturer and must not contain promotional claims.

Suspension of permit	**15.** The Authority may suspend the permit for advertisement of a medicinal product if it is satisfied that-
	(a) a registered medicinal product has been advertised in a manner which is false or misleading or does not comply with the provisions of the Act and these Regulations;
	(b) the permit holder has contravened these Regulations or any provision of the Act;
	(c) the permit holder made a false or misleading statement or misrepresentation in the application; or
	(d) renewal of permit has been defaulted beyond the validity period.
Notice of suspension	**16.** -(1) Any suspension shall be effected upon a written notice thereof.
	(2) The notice for suspension of a permit as set out in the Fifth Schedule of these Regulations shall-
	(a) set out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken; and
	(b) require the permit holder to show cause as to why the suspension shall not be effected.
Suspension or cancelation of permit without notice	**17.** -(1) The Authority may cancel or suspend the permit without prior notice if it is necessary to do so in order to protect public health.
	(2) The permit holder may apply to the Authority, in writing, that the cancelation or suspension be uplifted.
	(3) The Authority may, within thirty (30) days after the date of receiving the application, review its decision.
Restoration of permit	**18.** Pursuant to the provision of regulations 15 and 17, the Authority may, upon satisfaction that the reason giving rise to the suspension or cancellation of permit has been corrected or if such reason for suspension or cancelation was unfounded, reinstate the advertisement permit.
Refusal to grant permit	**19.** -(1) The Authority may refuse to grant advertisement permit if it is satisfied that-
	(a) after review of the application submitted in accordance with regulation 7, it appears that the applicant has not properly or sufficiently fulfilled the conditions of these Regulations; or
	(b) the promotional material does not conform to existing policies, orders or other national laws.
	(2) Pursuant to the provision of subregulation (1), where the

	Authority refuses to grant advertisement permit, the Director General shall inform the applicant in writing of such decision and the reasons thereof.
	(3) The refusal of advertisement permit shall constitute a prohibition on the advertisement and promotion of a product concerned throughout the country.
	(4) The information about all refusals and the reasons for such refusal may be made publicly accessible.
Cancellation or revocation of permit	**20.** -(1) The Authority may cancel or revoke the advertisement permit if-
	(a) it is not in the public interest that the advertisement shall be made or continue to be made available;
	(b) the medicinal product has been banned in Mainland Tanzania;
	(c) the validity of registration of a concerned medicinal product has expired; or
	(d) the marketing authorization of the concerned product has been suspended for a period of more than 6 months.
	(2) Pursuant to the provision of subregulation (1), a written notice of cancellation as prescribed in the Fifth Schedule shall then be issued to the permit holder stating the reasons for cancellation.

	PART III SAMPLES FOR PROMOTIONAL PURPOSES
Free samples	**21.** -(1) A person shall not sell or supply free samples of the product to the general public for promotional purposes.
	(2) Samples of products shall be provided only to a medical practitioner, dentist, veterinarian or pharmacist for products which they are entitled to prescribe or dispense.
	(3) Product samples must be well and clearly labelled or marked "Free Samples" – Not for Sale" and must be accompanied by a copy of the approved package insert.
	(4) Free samples of product must be of the smallest pack size registered by the Authority.
Samples of controlled drugs	**22.** Samples of controlled drugs containing narcotics or psychotropic substances shall not be offered to healthcare workers and general public.
Gifts and other inducements	**23.** -(1) A person shall not offer a product as a gift, benefit in kind or pecuniary advantage to healthcare workers, their families or employees as an inducement to prescribe, supply, administer, recommend, or purchase 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
	ADVERTISING ON THE INTERNET, SOCIAL MEDIA, TELEVISION AND RADIO PROGRAMMES
Internet advertising	**24.** -(1) Website providers shall ensure that promotional materials posted on the internet do not contravene these Regulations.
	(2) Promotion of prescription only medicines to the public using the internet or other digital channels is prohibited under these Regulations.
Social media	**25.** -(1) Under these Regulations, social media shall mean Facebook, YouTube, Twitter, WhatsApp, Instagram, Telegram, LinkedIn, Snapchat, Reddit, Blogs, TikTok, online televisions or any other related.
	(2) Advertisement and promotion of controlled drugs, prescription and pharmacy only medicines on social media referred to in subregulation (1) is prohibited.
	(3) Advertisement and promotion of over the counter and general sale medicines on social media referred to in subregulation (1) may be granted following approval by the Authority.
Television and radio programmes	**26.** -(1) A person shall not promote or advertise any medicinal product on television or radio programme without a written approval from the Authority.
	(2) Subject to subregulation (1), an application for approval shall be in accordance to regulation 7 of these Regulations.
	PART V
	TRADE FAIRS, EXHIBITIONS, SYMPOSIA AND OTHER MEETINGS
Trade Fair or Exhibition Permit	**27.** -(1) An application for a trade fair or exhibition permit shall be made by an applicant and shall be accompanied by the following- (a) a dully filled form prescribed in the Third Schedule of these Regulations; (b) a non-refundable application fee for foreign applicants as prescribed in the Fees and Charges Regulations in force;
	(2) After review of an application, the Authority may issue a permit as prescribed in the Fourth Schedule of these Regulations.
	(3) Subject to subregulation (1), an application for trade fair or exhibition permit shall be submitted fourteen days before commencement of the trade fair or exhibition.
	(4) Subject to subregulation (2), registered general sale and over the counter medicines to be displayed during trade fair or

	exhibition events may be sold to the general public.
	(5) Where an application referred to in subregulation (1) is made by a group of companies, each company shall pay a separate application fee.
	(6) General sale and over the counter medicines referred to in subregulation (4) shall be subject to payment of importation fees as prescribed in Fees and Charges Regulations in force.
	(7) The Authority may issue a special permit to the applicant who wishes to exhibit unregistered medicines during trade fair or exhibition events.
	(8) Subject to subregulation (7), a maximum of five samples per product in commercial pack may be allowed and shall be labelled "Not for Sale".
Symposia and other meetings	**28. -**(1) A person shall not organise or conduct symposia or any other meeting for product promotion unless after obtaining a permit as prescribed in the Fourth Schedule issued by the Authority.
	(2) A person wishing to conduct symposia or such meetings shall submit to the Authority an application in a prescribed form as provided under Third Schedule of these Regulations.
	(3) Presentation at symposia shall be factual, accurate, without omission and not biased towards any particular company's product.
	(4) Subject to subregulation (2), sale of products during such symposia or meetings is prohibited.
Sponsors of scientific symposia or meetings	**29.** Sponsorship of any scientific symposia or meeting or support to individual healthcare workers to participate in any symposia or meeting shall not be with a condition to promote any product.
	PART VI
	INSPECTION AND ENFORCEMENT
Inspection by Authority	**30.** -(1) The Authority may at any time conduct inspection of promotional materials at owners' premises, ports of entry, exhibitions, trade fair grounds, social media platforms, street banners and billboards, health facilities or any other facility deemed necessary.
	(2) The Authority may serve a notice to the owner of promotional materials requiring such person to furnish with such information concerning its compliance with these Regulations within such period as shall be specified in the notice.
	(3) Any reference to an inspection which the Authority is required or empowered to conduct by virtue of this regulation, shall be construed so as to include an inspection of such promotional materials within Mainland Tanzania at which promotion and advertising activities are carried out.
	(4) The Authority may, subject to the provisions of the Act, appoint inspectors necessary for the proper discharge of its functions

	under these Regulations and provide such terms and conditions for appointment as it shall be deemed appropriate.
Powers of inspectors	**31.** For the purposes of ensuring compliance or conducting inspections under these Regulations, the powers of inspectors shall be as prescribed under the Act.
	PART VII
	RECORDS KEEPING
Records to be kept by the applicant	**32.** -(1) An applicant shall have a duty to keep samples of promotional materials available, to respond to requests for information on promotional materials by providing such items as the Authority may request for consideration and to comply with any decisions taken by the Authority in respect of advertising and promotional materials and activities.
	(2) The Authority shall have powers to require copies of any published advertisement from any person appearing to be involved in its publication.
	(3) Subject to subregulation (2), all advertisers shall have arrangements to ensure that copies of all promotional materials are retained, either by themselves or on their behalf.
	(4) Records referred to in these Regulations shall be kept for a minimum of three years after the validity period.
Records to be kept by Authority	**33.** The Authority may keep such records of information which it receives from, or relating to promotional materials or activities as it considers appropriate and may, in particular, keep records relating to- (a) all authorizations under these Regulations; (b) notification of matters relating to promotional materials and activities; (c) inspections or requests for information; and (d) any other records as the Authority may deem appropriate.
	PART VIII
	GENERAL PROVISIONS
Objections to suspension and cancellation	**34.** -(1) The permit holder that-
	(a) objects to any suspension or cancellation of permit, or to any notice served; or
	(b) objects to the refusal of permit or the imposition of any condition, may notify the Director General of his desire to make written representations to, or be or appear before and be heard by, a person appointed by the Director General for that purpose.
	(2) Any notification of an objection pursuant to subregulation (1) shall be made within fourteen days (14) of the notice to which the

	notification pursuant to subregulation (1) relates.
	(3) Where the Authority receives a notification pursuant to subregulation (1), it shall appoint a person to consider the matter.
	(4) The person appointed pursuant to subregulation (3) shall determine the procedure to be followed with respect to the consideration of any objection.
	(5) The person appointed pursuant to subregulation (3) shall consider any written or oral objections made by the permit holder in support of its objection, and shall make a recommendation to the Authority.
	(6) A recommendation made pursuant to subregulation (5) shall be made in writing to the Authority, and a copy of it shall be sent to the permit holder or to its nominated representative.
	(7) The Authority shall take into account any recommendation made pursuant to subregulation (5).
	(8) Within fourteen (14) days of receipt of any recommendation made pursuant to subregulation (5), the Director General shall inform the permit holder whether he accepts the recommendation and, if he does not accept it, of the reasons for his decision.
	(9) Where the Director General is notified of an objection pursuant to subregulation (1)(a), before the date upon which the suspension or cancellation or the notice is due to take effect, the suspension or cancellation of a notice in respect of which the objection is made shall not take effect until-
	(a) the person appointed pursuant to subregulation (3) has considered the matter in accordance with the provisions of this regulation and made a recommendation; and
	(b) the Director General has informed the permit holder of his decision with regard to the recommendation pursuant to subregulation (8).
	(10) Subject to subregulation (9), where the Director General is notified of an objection pursuant to subregulation (1)(a), within the period specified in subregulation (2), to a suspension, cancellation or other notice which has already taken effect on the date the notification was made, the suspension, cancellation or notice in respect of which the objection is made shall cease to have effect until-
	(a) the person appointed pursuant to subregulation (3) has considered the matter in accordance with the provisions of this regulation and made a recommendation; and
	(b) the Director General has informed the permit holder of his decision with regard to the recommendation pursuant to subregulation (8).
	(11) The provisions of subregulation (10) shall not apply-
	(a) in relation to a suspension or cancellation or a notice served, which takes immediate effect in accordance with these Regulations; or

	(b) in any other case, where the Director General determines that it is necessary in the interests of the public for the suspension, cancellation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the permit holder.

Appeals	**35.** -(1) Any person aggrieved by the decision of the Authority may, within sixty (60) days appeal in writing to the Minister.
	(2) The appellant shall copy a notice of the appeal to the Authority who shall within fourteen (14) days submit a written response to the Minister and copy the appellant.
	(3) Where the Minister is of the opinion that a case has been made, he may summon parties for additional information or make a decision to allow or dismiss the appeal.
Offences and penalties	**36.** Any person who contravenes or fails to comply with these Regulations or directly or indirectly aids any other person to do what is prohibited under these Regulations shall be guilty of an offence and on conviction, shall be liable to the penalty prescribed under the Act.
Compounding of offences	**37.** -(1) The Director General, Inspector or any other authorized person may, subject to and in accordance with the provisions of these Regulations, if he is satisfied that a person has committed an offence against these Regulations, compound such offence by accepting from such person a sum of money in respect of which the offence has been committed.
	(2) The sum of money payable under subregulation (1) shall be two third of the maximum amount of the fine for the offence as prescribed in the Act.
	(3) The power conferred by this regulation shall be exercised where a person admits that he has committed an offence and agrees in writing in the form prescribed in the Sixth Schedule to the offence being dealt with under this regulation.
	(4) The Director General or officer exercising powers under this regulation shall give to the person from whom he receives any sum of money under subregulation (2) a receipt which shall be in a prescribed form.
	(5) Any sum of money received under this regulation shall be paid to the Authority.
	(6) If any proceedings are brought against any person for an offence against these Regulations, it shall be a good defence if such person proves that the offence with which he is charged has been

	compounded under this regulation.
Repealed of GN number 160 of 2010	**38.** The Tanzania Food, Drugs and Cosmetics (Control of Drugs and Herbal Drugs, Promotions) Regulations, 2010 are hereby repealed.

SCHEDULES

FIRST SCHEDULE

(Made under regulation 7 (1) and 8(2))

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

APPLICATION FORM FOR APPROVAL OF PROMOTIONAL MATERIALS

NB: Giving false or misleading information is a serious offence

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

Particulars of applicant

Applicant Name:	
Address:	
Postcode:	
Telephone:	
Mobile:	
E-mail address:	

Social media account (*where applicable*)	

Particulars of sponsor (if different from the applicant)

Name of Sponsor:	
Address:	
Postcode:	
Telephone:	
Mobile:	
E-mail address:	
Social media account (*where applicable*)	

Particulars of product

Distribution Category	Please tick the appropriate
Prescription Only Medicine	( )
Pharmacy Only Medicine	( )
General Sale Medicine	( )
Over the counter Medicine	( )
Controlled Drug	( )
Product Name	……
Active Ingredient(s) and Strength	……... …… …….. …….
Registration Number	
Type of Material	Please tick the appropriate box)
Poster ( ) Leaflet ( )	Outdoor/Billboard ( )

In/On Public Transport ( )	Magazine/Newspaper ( )
Literature ( )	Audio script ( )
Video Script ( )	Other ( ), Please specify
Intended audience (general public or healthcare workers): Please specify …….	
Intended means of distribution of the promotional material: ……	
Type of application	New application ( )
	Renewal application ( )
State any variations made to the approved advert	……
	…….

Attachments

A copy of the proposed advert (Script, Audio tape, CD, VCD, Video cassette)	( )
Current indications of use as indicated on the Summary of Products Characteristics (where applicable).	( )
Copy of any research/surveys/data mentioned in advertisement (Note – further evidence to be provided if requested)	( )
Copy of previous approval (*Applicable for renewal application*)	( )

Applicant's declaration

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

Signed: ……...…… **Date:**…….....

SECOND SCHEDULE

(Made under regulation 7 (4))

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

PERMIT FOR ADVERTISEMENT

Permit Number: ……

Permit is hereby granted for advertisement of medicinal product(s) as detailed below; -

Name of permit holder…….
Address……...
…….

Brand Name	Generic Name	Promotional Material	Registration Number	Target Audience

This permit is issued on ……... and shall remain valid up to …. ……

Name and Signature
DIRECTOR GENERAL

Conditions of the permit:

1. Product continues to comply with registration requirements as prescribed in the Tanzania Medicines and Medical Devices Act, Cap 219.
2. The permit must be returned to the Authority if canceled, invalidated or if registration of the medicine is withdrawn or when requested to do so by the Director General.
3. The promotional material shall comply with all relevant provisions of the Tanzania Medicines and Medical Devices Act, Cap 219 and its Regulations.
4. The permit holder shall ensure that application for renewal of permit is made 30 days before expiry period.
5. All variations of an approved advert shall be notified to the Authority and implemented upon approval issued by the Authority.
6. The Authority reserves the right to cancel or revoke this permit when the permit holder contravenes the requirements of the Act, relevant Regulations and for public interest.

THIRD SCHEDULE

(Made under regulation 27 (1) and 28 (2))

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

APPLICATION FORM FOR TRADE FAIR EVENT, EXHIBITION, SYMPOSIA OR OTHER MEETINGS

NB: Giving false or misleading information is a serious offence

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

Particulars of applicant

Applicant Name:	
Address:	
Postcode:	
Telephone:	
Mobile:	
E-mail address:	

Particulars of sponsor (if different from the applicant)

Name of Sponsor:	
Address:	
Postcode:	
Telephone:	
Mobile:	
E-mail address:	

Particulars of event

Type of event	Tick where applicable	Place of event	Target audience	Date(s) of event
Trade fair				
Exhibition				
Symposium				
Other meetings (please specify)				

Particulars of product

S/N	Name of Product	Registration Status		Registration number	Type of materials
		Registered	Unregistered (*indicate number of samples*)		

Add as many rows as necessary

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

This promotional event will be conducted at …… (mention place) for a duration of …… … (specify duration of time)

This form shall be accompanied by:

NB: Please tick or mark X on items below:

( ) A copy of adverts to be used at the trade fair activities
( ) A copy of presentation to be made at the symposia or meetings
( ) Proof of payment in case of trade fair and exhibitions

Applicant's declaration

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

Signed: ……...…… **Date**:…….....

FOURTH SCHEDULE

(Made under regulation 27 (2) and 28 (1))

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

PERMIT FOR TRADE FAIR EVENT, EXHIBITION, SYMPOSIA OR OTHER MEETINGS

Permit Number: ……

Permit is hereby granted for advertisement of medicinal product(s) in a trade fair event, exhibition, symposia or other meetings as detailed below; -

Name of permit holder…….
Address……...
…….

Type of event	Place of event	Target audience	Date(s) of event

Trade fair			
Exhibition			
Symposia			
Other meetings (please specify)			

This permit is issued on ……... and shall remain valid up to …. ……

Name and Signature
DIRECTOR GENERAL

Conditions of the permit:

1. Products to be displayed shall comply with requirements as prescribed in the Tanzania Medicines and Medical Devices Act, Cap 219.
2. The permit must be returned to the Authority if canceled, invalidated or when requested to do so by the Director General.
3. The promotional material shall comply with all relevant provisions of the Tanzania Medicines and Medical Devices Act, Cap 219 and its Regulations.
4. The Authority reserves the right to cancel or revoke this permit when the permit holder contravenes the requirements of the Act, relevant Regulations and for public interest.

FIFTH SCHEDULE

(Made under regulation 16 (2) and 20 (2))

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

NOTICE OF SUSPENSION OR CANCELLATION OF ADVERTISEMENT PERMIT

Pursuant to Regulation 16 (2) and 20 (2) of the Tanzania Medicines and Medical Devices (Control Human and Veterinary Medicines Promotion) Regulations, notice of suspension/cancellation of advertisement permit number ……is hereby issued to ……...for the reasons stated below:-

1.……

2.……

3.……

The suspension shall remain in force for a period of ……..… days from the date of this notice and may be uplifted if appropriate corrective actions have been instituted as directed by the Authority.

Issued on this……...day of …… year ……..

Name and Signature
Director General

SIXTH SCHEDULE

(Made under regulation 37 (3))

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

COMPOUNDING FORM

TMDA No.....
Station .....
Date .....

Date……. Name of Premises…….…….……..……,

of Address and Contact No(s) ..…….……..,
……..

I,…….…….. (name of Incharge/owner) do hereby admit that I have contravened section(s) .....of the Tanzania Medicines and Medical Devices Act, Cap 219 (state the provision of law contravened)

by……
……..……..

(state particulars of offence) and hereby declare that rather than being prosecuted for the commission of the aforementioned offence, on my own free will, I admit that the said offence be compounded under Regulation 12 of the Fees and Charges aforementioned

I, ..., ... (name and designation of officer compounding the offence) for Tanzania Medicines and Medical Devices, in exercise of the power conferred upon me by Regulation 12 of the Fees and Charges, hereby order that …….....(name of the offender) to pay the sum of TZS..... Where by (TZS……) by way of compounding and TZS…..…..……..by way of disposal charge being 25% of the value of condemned products and/or 2% FOB and 15% penalty of (unpaid fee) for imported goods.(Listed exhibit(s)/products on attached confiscation form(s) are forfeited to the Government)

Dated this……..…day of …….. 20.....

……
……

(Signature of offender) (Signature of officer compounding)

……. …….

(Signature of witness) (Signature of witness)

NOTE:

This form shall be issued in duplicate and the original copy shall be served to the offender.

Dodoma
…..., 2025

MOHAMED OMARY MCHENGERWA
Minister For Health