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

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REGULATIONS

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(Made under section 122[1][e])

THE TANZANIA FOOD, DRUGS AND COSMETICS (REGISTRATION OF MEDICINAL PRODUCTS) REGULATIONS, 2015

ARRANGEMENT OF REGULATIONS

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

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(Made under section 122[1][e])

THE TANZANIA FOOD, DRUGS AND COSMETICS
(REGISTRATION
OF MEDICINAL PRODUCTS) REGULATIONS, 2015

PART I
PRELIMINARY PROVISIONS

Citation

1. These regulations shall be cited as the Tanzania Food, Drugs and Cosmetics (Registration of Medicinal Products) Regulations, 2015.

Application and scope

2. These regulations shall be used for registration of medicinal products and shall be applied in Mainland Tanzania.

Interpretation

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

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

"active pharmaceutical ingredient" means a substance or compound that is intended to be

used in the manufacture of a pharmaceutical product as a therapeutically active compound (ingredient);

"applicant" means a person who submits an application for registration of a medicine, an update or amendment to an existing registration to the Authority who may be a manufacturer or a person to whose order and specifications, the product is manufactured. After the product is registered the applicant shall be "marketing authorization holder";

"approve" or "approval" means official consent by the Authority as an acceptance of a medicinal product or practices related to that medicinal product to circulate in the Tanzanian market;

"Authority" means the Tanzania, Food and Drugs Authority or in its acronym "TFDA" established by Section 4 of the Act;

"batch" or "lot" in relation to a medicine means a defined quantity of a medicine manufactured in a single manufacturing cycle and which has homogeneous properties;

"batch manufacturing record" or its acronym "BMR" means all documents associated with the manufacture of a batch of bulk product or finished medicinal product;

"batch number" or "lot number" means a unique number or combination of numbers or cyphers allocated to a lot or a batch by the manufacturer,

"bioequivalence" means the absence of a significant difference in the bioavailability between two

pharmaceutically equivalent products under similar conditions in an appropriately designed study;

"composition" means the ingredients of which the product consists, proportions, degree of strength, quality and purity in which those ingredients are contained;

"container" means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain in it, not being a capsule or other article in which the product is or is to be administered or consumed, and, where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle;

"country of origin" means a country in which the medicinal product has been manufactured ;

"Director General" means the head of the Authority;

"generic medicinal product" means a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies;

"Good Manufacturing Practice" or its acronym "GMP" is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Authority;

"label" means any tag, brand, mark, pictorial or

other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a container of any medicinal product;

"manufacture" means all operations that involve preparation, processing, filling, transforming, packaging, and repackaging and labelling of medicinal products;

"manufacturer" means a person or a firm that is engaged in the manufacture of medicinal products;

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

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

"Minister" means the minister for the time being responsible for health;

"paediatric investigation plan" means a research and development programme aimed at ensuring that the necessary data are generated for determining the conditions in which a medicinal product may be authorised to treat

the paediatric population exclusively;

"paediatric population" means that part of the population exclusively aged between birth and 18 years ;

"recognized pharmacopeia" means current version of , British Pharmacopeia, United States Pharmacopeia, European Pharmacopeia, Japanese Pharmacopeia and International Pharmacopeia or approved National Pharmacopeia;

"registration certificate" means a document for official approval of a medicinal product for circulation in the market;

"registration" or "marketing authorization" means an official approval of the medicinal product to be marketed or distributed in Tanzania;

"sale or sell" means sell by wholesale or retail and includes to import, offer, advertise, keep, expose, display, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale or prepare or process for purpose of sale, and barter or exchange supply or dispose of to any person whether for a consideration or otherwise;

"Site Master File" means a document prepared by the manufacturer containing specific and factual good manufacturing practice information about the production and/or control of pharmaceutical manufacturing operations carried out at a named site and any closely integrated operations at adjacent and nearby buildings;

''substantial evidence'' means evidence consisting

of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

PART II
REGISTRATION OF MEDICINAL PRODUCTS

Restriction for sale of unregistered medicinal product

4.-(1) No person shall manufacture for sale, sell, offer, supply or import medicinal products by either wholesale or retail unless it is in accordance with the provisions of these Regulations, and that person holds the appropriate license or permit required and issued by the Authority.

(2) Notwithstanding the provision of subregulation 4(1), these Regulations shall not apply to-0

(a) any medicinal product prepared in a pharmacy and is done by or under the supervision of a pharmacist in accordance with a prescription given by a medical practitioner, dentist or a veterinarian;

(b) any product prepared in a hospital pharmacy in accordance with the formulas of a pharmacopoeia, and

intended to be supplied directly to patients served by the pharmacy in concern and commonly referred to as the official formula;

(c) medicinal products intended to be used in research and development studies, without prejudice to the provisions of the Regulations on clinical trials in force;

(d) any medicinal product prepared by a medical practitioner or dentist for administration or supply to his particular patient;

(e) any medicinal product prepared by a medical practitioner or dentist at the request of another medical practitioner or dentist for administration to a particular patient of that other medical practitioner or dentist;

(f) any medicinal product prepared by a veterinarian specially for administration to a particular animal which is under his care;

(g) any medicinal product prepared by a veterinarian at the request of another veterinarian for administration to a particular animal or group of animals under the care of that other veterinarian;

(h) any medicinal product prepared in a pharmacy and is done by or under the supervision of a pharmacist in which the pharmacist is requested by or on behalf of that person to do so in accordance with the pharmacist own judgment as to the

treatment required and that person is present in the pharmacy at the time of the request in pursuance of which that product is prepared;

(i) any medicinal product prepared and stocked with a view to dispensing as mentioned in paragraphs (a) and (h);

(j) any medicinal products prepared and stocked in a hospital pharmacy by or under the supervision of a pharmacist with a view to dispensing as mentioned in paragraph (a); or

(k) any preparation made by a traditional health practitioner registered under the Traditional and Alternative Medicines Act, which relates to a traditional medicine specifically prepared for administration, or supply to a particular patient;

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(l) any person who prepares any preparation shall be duty bound and shall be held liable for any harm to the patient brought by the medicine.

Application for registration of medicinal products

5.-(1) Every application for registration of a medicinal product shall be made in hard and electronic copies and shall be accompanied by the following:

(a) cover letter;

(b) a dully filled in application FORM MP A as provided in First Schedule to these regulations;

(c) a table of contents listing all sections of

the dossier and documents and their corresponding page numbers;

(d) medicinal product dossier as per requirements and formats prescribed in guidelines for registration of human, veterinary, herbal, human biological, veterinary biological and any other relevant guidelines in force at the time of submission;

(e) an original Certificate of Pharmaceutical Product (WHO Format) on official papers of the issuing competent authority;

(f) adequate quantity of samples to allow full analysis of the product as per product specifications plus one repeat analysis;

(g) a site master file as stipulated by the GMP regulations in force at the time of application;

(h) non refundable application fees for registration of medicinal products in Tanzania and GMP inspection fees for manufacturing facilities as described in Fees and Charges Regulations in force.

(2) The application referred to in sub regulation (1) shall include the particulars of the person with appropriate knowledge of all aspects of the medicine who shall be responsible for communication with the Authority.

(3) All applications and supporting documents shall be in English or Kiswahili and, any other submitted documents which are in any language other than English or Kiswahili shall be accompanied by a certified or notarized English or Kiswahili translation.

(4) A separate and complete application for

registration of medicinal products shall be submitted for each medicinal product

(5) Medicinal products with different active ingredients, strengths, dosage forms, site of manufacture or proprietary names, shall for the purposes of these Regulations be considered to be different products and the same shall require separate applications.

(6) Notwithstanding the requirement of sub regulation (5), all parenteral preparations in different pack sizes shall require separate applications.

Data requirements

6.-(1) All applications for registration of medicinal products shall comply with the technical requirements as determined by the Authority and such applications shall be accompanied by data to demonstrate quality, safety and efficacy based on basic principles and requirements described below-

(a) the chemical, pharmaceutical and biological data shall be provided and shall include for the active pharmaceutical ingredient(s) and for the finished medicinal product all of relevant information on: the development, the manufacturing process, the characterization and properties, the quality control operations and requirements, the stability as well as a description of the composition and presentation of the finished medicinal product;

(b) two main sets of information shall be provided, dealing with the active pharmaceutical ingredient(s) and with the finished medicinal product, respectively;

(c) detailed information on the starting and raw materials used during the manufacturing operations of the active pharmaceutical ingredient(s) and on the excipients incorporated in the formulation of the finished medicinal product shall be provided;

(d) all the procedures and methods used for manufacturing and controlling the active pharmaceutical ingredient(s) and the finished medicinal product shall be described in sufficient details;

(e) where applicable the monographs of a recognized pharmacopeia applicable to substances, preparations or pharmaceutical forms presented shall be used;

(f) in cases where starting and raw materials, active pharmaceutical ingredient(s), excipients and finished products are not described in recognized pharmacopeia the applicant shall submit a copy of the monograph used accompanied by the validation of the analytical procedures contained in the monograph;

(g) for materials originating from ruminants, specific measures concerning the prevention of the transmission of animal spongiform encephalopathy's during each step of the manufacturing, shall be demonstrated;

(h) any special apparatus and equipment, which may be used at any stage of the manufacturing process and control operations of the medicinal product, shall be described in adequate details;

(i) for adventitious agents, information assessing the risk with respect to potential contamination with adventitious agents, whether they are non-viral or viral, as laid down in relevant guidelines as well as in relevant general monographs and general chapters of pharmacopoeias shall be provided;

(j) pharmacological and toxicological tests results shall be provided and must show the potential toxicity of the product and any dangerous or undesirable toxic effects that may occur under the proposed conditions of use in human beings and the pharmacological properties of the product, in both qualitative and quantitative relationship to the proposed use in human beings;

(k) clinical data shall be provided to enable a sufficiently well-founded and scientifically valid opinion to be formed as to whether the medicinal product is efficacious and;

(l) bioavailability study reports, comparative bio-availability, bioequivalence study reports, reports on in vitro and in vivo correlation study, and bio-analytical and analytical methods shall be provided.

New medicinal products with use in paediatric population

7. All applications for registration of new medicinal products intended for use in pediatric population shall be accompanied by a Paediatric Investigation Plan (PIP).

Authenticity of

8.-(1) A document submitted shall be

documents and integrity of data

considered authentic when bearing a signature and seal attesting that it is genuine and official.

(2) The Authority shall cause an application for registration of a medicinal product to be rejected if it is satisfied that the submitted documents are not authentic or integrity of data is questionable.

Accountability of the applicant and marketing authorization holder

9.-(1) The applicant shall be accountable for all information supplied in support of his application for registration of the product and variations thereof.

(2) The marketing authorization holder shall be accountable for-

(a) manufacturing the product in compliance with the specifications approved according to provisions of these Regulations;

(b) updating, when necessary, summary of product characteristics and package inserts for the purpose of enabling a correct and safe use of the product;

(c) communicating the variations to the Authority within the framework of the relevant provisions of the guidelines;

(d) providing responses to the issues requested by the Authority, in relation to a registered product;

(e) to carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the Authority;

(f) ensuring that the product continues to comply with the requirements prescribed in the Act and these regulations including

payment of annual retention fees prescribed in Fees and Charges Regulations in force.

Safe custody and confidentiality of information

10.-(1) The Authority shall ensure safe custody of information related to the registration of medicinal products submitted by applicants and marketing authorization holder.

(2) All information submitted shall be treated confidential and shall not be disclosed to any third party without a written consent of the applicant or marketing authorization holder.

Evaluation of medicinal products

11.-(1) The Authority shall, upon being satisfied by the application, cause the same to be evaluated to assess compliance with safety, quality and efficacy requirements.

(2) The Authority may, during the evaluation of the product, require the applicant to submit additional samples, documents, information, data or clarification as the case may be.

(3) Where the Authority requires additional samples, documents, information, data and or clarification pursuant to sub-regulation (2), the processing of the application shall not proceed until such time when the applicant makes submission.

(4) Where the applicant fails to submit pursuant to sub regulation (2), within the period of six months from the date of request letter, the application shall be rendered withdrawn.

(5) Pursuant to the requirements of sub-regulation (4), the applicant may by giving reasons request for extension of time for submission of additional samples, documents, information, data

and or clarification requested by the Authority.

(6) An application withdrawn pursuant to sub regulation (4) shall only be considered for registration upon submission of a new application as per the requirements of these regulations.

(7) During the course of evaluation, the Authority shall as it may deem necessary conduct on-site inspection and causal inspection of the non-clinical studies, clinical trials, bio-studies and production site inspection to confirm the authenticity, precision and integrity of information and data submitted.

Registration of medicinal products

12.-(1) After evaluation of an application, the Authority may present the outcome of evaluation and recommendations before the technical committee for registration of medicinal products for consideration.

(2) The recommendations arising from the deliberations of the technical committee responsible for registration matters for registration of medicinal products shall then be presented to the Director General for final approval.

(3) Upon receiving the recommendations of the technical committee, the Director General may approve the recommendations as they are or alter the recommendations for public interest and cause the product to be fully or provisionally registered if satisfied that the product is suitable for the purpose for which it is intended.

(4) Approval issued for provisional registration shall specify the conditions which need to be fulfilled by marketing authorization holder to

acquire full registration.

(5) Upon approval of registration to a medicinal product, the Authority shall-

(a) enter in the register the prescribed particulars of the medicinal product;

(b) allocate a registration number to the medicinal product;

(c) Issue to the marketing authorization holder a certificate of full or provisional registration as per format prescribed in the Second Schedule to these regulations.

(6) The Authority shall cause to be published in the *Government Gazette* a list of registered medicinal products specifying the name under which the product is registered, the qualitative and quantitative content of its active components, the name of the marketing authorization holder and the registration number.

Validity of registration

13.-(1) A certificate of full registration issued under regulation (12) sub-regulation (5) (c) shall, unless earlier suspended or revoked, and subject to payment of prescribed annual retention fees be valid for a period of five years from the date of issuance and may thereafter be renewed.

(2) Notwithstanding of the provision of subregulation (1), a certificate of provisional registration shall be valid for a period specified in the certificate and that period shall not exceed three years.

Establishment of expert committee

14.-(1) The Director General may establish

an expert committee for the purpose of advising on specific issue related to registration of medicines.

(2) The committee established under sub regulation (1) shall execute its functions based on the terms of reference of the Director General.

Application for variation of registered product

15.-(1) Any variation to a registered medicinal product shall be notified to the Authority by filling in application form number MP B as set out in First Schedule to these regulations.

(2) An application for variation shall be submitted as per the requirements set out in the Guidelines for Variation of Registered Medicinal Products in force at the time of submission.

(3) A payment for major variation shall be made in accordance with the Fees and Charges Regulations in force.

(4) Distinction between minor and major variation will be made in accordance with the guidelines.

Retention of medicinal product in the register

16. Every marketing authorisation holder shall, in addition to the fees related to registration of each medicinal product, pay annual retention fees before 31st January of each calendar year.

Application for renewal of registration

17.-(1) Application for renewal of registration shall be made to the Authority at least ninety days before its expiry by filling in the application form number MP A as set out in the First Schedule to these Regulations.

(2) A grace period for renewal shall extend

to ninety days after the specified expiry date.

(3) Defaulters shall pay a penalty as stipulated in Fees and Charges Regulations in force after the expiry of grace.

(4) The application shall be in hard and electronic copies and shall be accompanied by:

(a) Batch Manufacturing Record (BMR) of the largest production scale batch manufactured within six months before the submission of the application;

(b) current specifications of finished product and standard testing procedures;

(c) adequate quantity of samples to allow for full specification analysis plus one repeat analysis with their respective certificates of analysis;

(d) two specimens each of package insert and colour printed packaging materials;

(e) non refundable application fees as prescribed in the Fees and Charges Regulations in force; and

(f) non refundable Good Manufacturing Practice inspection fees as prescribed in the Fees and Charges Regulations in force and the current site master file if the facility has not been inspected and approved by the Authority within the last three (3) years.

Submission of post-marketing quality and safety reports

18.-(1) Pursuant to regulation 9 (2), every marketing authorisation holder shall be duty bound to conduct periodic post-marketing surveillance and safety studies.

(2) The post-marketing surveillance and

adverse effects reports shall be submitted to the Authority after every two (2) years for evaluation and determination of risk benefit profile of the registered products every two years.

(3) Failure to submit the reports shall render the registration of the medicinal product suspended.

Suspension of registration

19. The Authority may suspend registration of a medicinal product if it is satisfied that:

(a) A registered medicinal product has been advertised in manner which is false or misleading or does not comply with the provisions of the Act and regulations made thereunder;

(b) The marketing authorization holder has contravened these regulations or any provision of the Act;

(c) the marketing authorisation holder made a false or misleading statement or misrepresentation in the application;

(d) the marketing authorisation holder has failed to comply with the terms and conditions of the registration as provided in certificate of drug registration;

(e) the marketing authorisation holder has failed to pay the prescribed retention fees referred to in regulation 15 within the prescribed time;

(f) the marketing authorisation holder has failed to submit periodic post-marketing surveillance reports as prescribed in regulation 17;

(g) the marketing authorisation holder,

intentionally and without justifiable cause has failed to submit reports on adverse effects and;

(h) Renewal of registration has been defaulted beyond the specified grace period.

Notice of suspension

20.-(1) Any suspension shall be effected upon a written notice thereof.

(2) The notice for suspension of registration of a medicinal product as set out in form MP C of First 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;

(b) require the marketing authorization holder to show cause as to why the suspension should not be effected.

Suspension or cancelation of registration without notice

21.-(1) The Authority may cancel or suspend the registration of a medicinal product without prior notice if it is necessary to do so in order to prevent injury to the health or safety of patients, users or other persons.

(2) The marketing authorization holder may apply to the Authority, in writing, that the cancelation or suspension be uplifted.

(3) The Authority may, within sixty (60) days after the date of receiving the application, review its decision.

Restoration of

22. Pursuant to the provision of regulations

registration

18 and 20, the Authority may, upon satisfaction that the reason giving rise to the suspension or cancellation of registration has been corrected or if such reason for suspension or cancelation was unfounded, reinstate the registration of a medicinal product.

Refusal to grant marketing authorisation

23.-(1) The Authority shall refuse to grant marketing authorisation of a medicinal product if it is satisfied that-

(a) after verification of the particulars and evaluation of documents submitted in accordance with regulation 5, it appears that the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product, or

(b) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such medicine are inadequate to preserve its identity, strength, quality, and purity; or

(c) particulars or documents provided by the applicant in accordance with Regulation 5 are incorrect or if the labelling and package inserts proposed by the applicant are not in accordance with regulations 24 and 25.

(2) Pursuant to the provision of subregulation (1), where the Authority refuses to grant registration to a medicinal product, the Director General shall inform the applicant in writing of such decision and the reasons thereof.

(3) The refusal of a marketing authorisation shall constitute a prohibition on the placing on the market of the medicinal 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 marketing authorization

24.-(1) The Authority may cancel or revoke the marketing authorization of a registered medicinal product if-

(a) it is not in the public interest that the registered medicinal product should be made or continue to be made available;

(b) the medicinal product has been banned in Mainland Tanzania;

(c) the medicinal product no longer meets the quality, safety and effectiveness requirements; and

(d) the marketing authorization has been suspended for a period of more than 12 months.

(2) Pursuant to the provision of subregulation (1), a written notice of cancellation as perform MP C of First Schedule shall then be issued to marketing authorization holder stating the reasons for cancellation.

PART III

LABELLING, PACKAGE INSERT, INFORMATION LEAFLET AND LANGUAGES

Labelling

25.-(1) Every container of medicinal products intended to be marketed in the country shall be labelled in English or Kiswahili or both.

(2) The label of an immediate outer container of a medicinal product shall contain at minimum the following information:

(a) the brand or trade name of the medicinal product;

(b) a list of active pharmaceutical ingredient(s) (using International Non-proprietary Names if applicable) showing the amount of each present in a dosage unit, and a statement of the net contents of the container.

(c) dosage form

(d) method and route of administration;

(e) list of excipients known to have safety concerns for some patients;

(f) indication(s) and recommended dosage, where practicable;

(g) the batch number assigned by the manufacturer;

(h) the manufacturing and expiry dates in an uncoded form;

(i) storage conditions or handling instructions;

(j) precautions that may be necessary;

(k) directions for use and any warnings or precautions that may be necessary;

(l) the name and address of the manufacturer;

(m) the name and address of the marketing authorisation holder if different from the manufacturer

(n) proposed distribution category or schedule of

medicines;

(o) the word 'sterile' for sterile medicinal products.

(3) In the case of containers of less than or equal to 10ml capacity that are marketed in an outer pack such as a carton, and the outer pack bears all the required information, the immediate container shall contain the information as prescribed in paragraphs (a), (b), (c), (g), (i) and (j) of sub regulation (1) to this regulation or a logo that unambiguously identifies the marketing authorisation holder and the name of the dosage form or the route of administration.

(4) In case of blisters and strips, the label shall be printed with the following minimum information;

(a) generic and trade names, strength and pharmaceutical form of the finished pharmaceutical product;

(b) name of the manufacturer;

(c) the batch number assigned by the manufacturer and;

(d) the manufacturing and expiry dates in an encoded form.

(5) Subject to sub regulation (2) of this regulation, the marketing authorisation holder shall be required to print the Tanzania registration number on the label after obtaining marketing authorisation.

(6) Subject to sub regulation (1), (2), (3) and (4) of these regulations, the batch number, manufacturing and expiry dates shall be embossed, engraved or printed in manner that is indelible on the inner and outer packaging.

Package inserts

26.-(1) The package insert aimed at medical practitioners and other health professionals shall be drawn up in accordance with the summary of product

characteristics which shall include the following-

(a) name of the medicinal product;
(b) description of the medicinal product;
(c) Anatomic Therapeutic and Chemical Classification (ATC);
(d) distribution Category;
(e) qualitative and quantitative composition;
(f) pharmaceutical form of the product;
(g) clinical particulars;
(h) pharmacological properties;
(i) pharmaceutical particulars;
(j) list of excipients;
(k) name and address of the marketing authorization holder;
(l) name and address of the manufacturer if different from marketing authorization holder;
(m) registration number(s) to be included after approval;
(n) date of revision of the text.

(2) In case of generic medicine, the package insert shall be comparable to that of the corresponding innovator product.

(3) The package insert shall not be changed without the approval of the Authority.

(4) All medicinal products with potential for long term use and all general sale medicines shall contain a patient information leaflet with information presented as prescribed in form number MP D in First Schedule to these Regulations.

(5) The information contained in the package inserts and patient information leaflet shall be legible, indelible, comprehensible written in English or Kiswahili languages or both Kiswahili and English.

PART IV

GENERAL PROVISIONS

Appeals and review

27.-(1) Any person aggrieved by a decision of the Authority may, apply for review of the decision to the Authority showing grounds for dissatisfaction within sixty (60) days from the date of notice.

(2) The Authority shall, within 45 days from the date of receiving the application, shall review, reject or vary its own decision.

(3) Notwithstanding the provision of sub regulation (1), the applicant shall not be barred from appealing to the Minister without applying for review to the Authority.

(4) If a person is dissatisfied with the decision after review, he may appeal to the Minister whose decision shall be final.

Offence

28. Any person who contravenes any provision of these Regulations or directly or indirectly aids any other person to do what is prohibited under these Regulations commits an offence under the Act.

Penalty

29. Any person found guilty of an offence under these Regulations shall be liable to the sanctions prescribed in the Act.

FIRST SCHEDULE

FORM MP A

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE

(Made under Regulation 5(1) (b) and 16(1))

APPLICATION FORM FOR REGISTRATION MEDICINAL PRODUCT

Application Number	TFDA use only
Date of submission of the dossier	TFDA use only
ADMINISTRATIVE INFORMATION	
PARTICULARS OF THE PRODUCT	
1.0	Product category: Human medicine Veterinary medicine
1.1	Type of the medicinal product application New Renewal* Indicate registration number ** If variation has been made, information supporting the changes should be submitted. See TFDA variation guidelines for registered medicinal products.*
1.2	Proprietary Name
1.3	International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API)
1.4	Strength of Active Pharmaceutical Ingredient (API) per unit dosage form:
1.5	Name and address (physical and postal) of Applicant
(Company) Name:	

Address: Country: Telephone: Telefax: E-Mail:	
1.6	Pharmaceutical Dosage form* and route of administration* * List of standard terms for dosage forms and routes of administration is available in the TFDA guidelines on submission of documentation for registration of human medicinal products
1.6.1	Dosage form:
1.6.2	Route(s) of administration (use current list of standard terms)
1.7	Packing/pack size:
1.8	Visual description *(Add as many rows as necessary)*
1.9	Proposed shelf life (in months):
1.9.1	Proposed shelf life (after reconstitution or dilution):
1.9.2	Proposed shelf life (after first opening container):
1.9.3	Proposed storage conditions:
1.9.4	Proposed storage conditions after first opening:
1.10	Other sister medicinal products registered or applied for registration
1.10.1	Do you hold Marketing Authorization (s) of other medicinal product (s) containing the same active substance (s) in the TFDA? If yes state; ▪ Product name (s), strength (s), pharmaceutical form (s): ▪ Partner States where product is authorised: ▪ Marketing authorisation number(s): ▪ Indication(s):
1.10.2	Have you applied for Marketing Authorization of medicinal product (s) containing the same active substance (s) in TFDA? ▪ Product name (s), strength (s), pharmaceutical form (s): ▪ Indication(s):
1.11	Pharmacotherapeutic group and ATC Code
1.11.1	Pharmacotherapeutic group:
1.11.2	ATC Code: (*Please use current ATC code)*

1.11.3	If no ATC code has been assigned, please indicate if an application for ATC code has been made: ☐
1.12	Distribution category: Controlled Drug ☐ POM ☐ Pharmacy Only ☐ OTC ☐ General sale ☐ *(Applicants are invited to indicate which categories they are requesting, however TFDA reserves the right to change and/or apply only those categories provided for in their national legislation)*
1.13	Country of origin:
1.14	Product Marketing Authorisation in the country of origin (Attach Certificate of Pharmaceutical Product from National Medicines Regulatory Authority). If not registered, state reasons

☐Authorised Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: ☐ Refused Country: Date of refusal (dd-mm-yyyy): Reason for Refusal:	☐ Withdrawn (by applicant after authorisation) Country: Date of withdrawal (dd-mm-yyyy): Proprietary name: Reason for withdrawal: ☐ Suspended/revoked (by competent authority) Country: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:

1.15	List ICH countries and Observers where the product is approved (attach evidence).
1.16	Name(s) and complete physical address(es) of the manufacturer(s)
1.16.1	Name(s) and physical address(es) of the manufacturing site of the finished pharmaceutical product (FPP), including the final product release if different from the manufacturer. Alternative sites should be also declared here. *All manufacturing sites involved in the manufacturing process of each step of the finished product, stating the role of each including quality control / in-process testing sites should be listed.* (Add as many rows as necessary

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

1.16.2	Name(s) and physical address(es) of the manufacturer(s) of the active pharmaceutical ingredient(s) (API) *(Add as many rows as necessary)* *All manufacturing sites involved in the manufacturing process of each source of active substance, including quality control / in-process testing sites should be listed.*
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.17	Name and address (physical and postal) of the Brokers and Suppliers (*if applicable)*
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.18	Name and address (physical and postal) of the person or company responsible for pharmacovigilance
Name: Company name: Address: Country: Telephone: Telefax: E-Mail:	
1.19	State the reference/monograph standard such as British Pharmacopeia, United States Pharmacopeia (USP), European Pharmacopeia (Ph.Eur), Japanese Pharmacopeia (JP), International Pharmacopeia (Ph.Int), In-house monograph e.t.c. used for Finished Medicinal Product.
1.20	Qualitative and Quantitative composition of the active substance(s) and excipient(s) *A note should be given as to which quantity the composition refers (e.g. 1 capsule).*

Name of active ingredient(s)*	Quantity / dosage unit	Unit of measure	Reference/monograph standard
1.			
2.			
3.			
e.t.c			
Name Excipient(s)			
1.			

2.			
3			
e.t.c			

*Note: * Only one name for each substance should be given in the following order of priority: INN**, Pharmacopoeia, common name, scientific name*
*** The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.*
Details of averages should not be included in the formulation columns but should be stated below:
- Active substance(s):
- Excipient(s):

1.21	Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the product were conducted. *(If applicable)*

Name:
Company name:
Address:
Country:
Telephone:
Telefax:
E-Mail:

DECLARATION BY THE APPLICANT

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.

I also agree that I shall carry out pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to TFDA.

I further agree that I am obliged to follow the requirements of the Legislations and Regulations which are applicable to medicinal products. I also consent to the processing of information provided by TFDA.

It is hereby confirmed that fees have been paid according to the Fees and Charges Regulations.

Name: _____

Position in the company: _____

Signature: _____

Date: _____

Official stamp: _____

**** Note: If fees have been paid, attach proof of payment***

GN. No. 314 (contd.)

FORM MP B

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE

(Made under Regulation 15(1))

APPLICATION FORM FOR VARIATION OF A REGISTERED MEDICINAL PRODUCT

1. Proprietary name
1.1 Name of the active ingredient(s) (International Non-proprietary Name in English)
1.2 Pharmacotherapeutic classification (Anatomic-Therapeutic Classification system)
2. Pharmaceutical Dosage form:
3. Type of change(s) (*State which type of Variation):*
3.1 Other Application(s) *(Please provide brief information on any ongoing variation or other variation(s) submitted in parallel, or renewal application(s), or line-extension(s))*
3.2 Scope *(Please specify scope of the change(s) in a concise way)*
3.4 Background for change & Justification for Consequential change(s) (If applicable) *Please give brief background explanation for the proposed change(s) to your marketing authorization as well as a justification in case of consequential change(s)*

3.5 Present *(Please specify precise present wording or specification)*	Proposed *(Please specify precise proposed wording or specification)*

In the case of changes to the Summary of Product Characteristics and/or package leaflet, applicants should always enclose a working model clearly showing the differences (new text and deleted text) between the proposed new version and the current text, previous version or reference text.

4. Details of applicant (Must be the holder of the marketing authorization/registration certificate) Name: Business Address: Postal Address: Country: Phone: Fax: Email:

GN. No. 314 (contd.)

Form MP C

(Made under Regulation 20(2) and 24(2))

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE

NOTICE OF SUSPENSION/CANCELLATION OF MARKETING AUTHORIZATION OF A MEDICINAL PRODUCT

Pursuant to Regulation 20 (2) of the Tanzania Food, Drugs and Cosmetics (Registration of Medicinal Products) Regulations, 2014, notice of suspension/cancellation of marketing authorisation of …… …… is hereby issued to …… …….. for the reasons stated below:-

1. ……
   ……
2. ……
   ……
3. ……
   ……

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

Issued by ……. the **Director General** on this ….. day of ……

FORM MP D

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE

(Made under regulation 26 (4))

PATIENT INFORMATION LEAFLET

TEMPLATE FOR PATIENT INFORMATION LEAFLET

{(Proprietary) name strength pharmaceutical form}[1]
{Active substance(s)}

Read all of this leaflet carefully before you start <taking><using> this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your <doctor, health care provider><or><pharmacist>.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider><or><pharmacist>.>

In this leaflet:

(a) What {product name} is and what it is used for
(b) Before you <take><use> {product name}
(c) How to <take><use> {product name}
(d) Possible side effects
(e) How to store {product name}
(f) Further information

[Delete sections that are not applicable]

a) WHAT {PRODUCT NAME} IS AND WHAT IT IS USED FOR

b) BEFORE YOU <TAKE><USE> {PRODUCT NAME}

Do not <take><use> {product name}

- <if you are allergic (hypersensitive) to {active substance(s)} or any of the other ingredients of {product name}.>
- <if ...>

Take special care with {product name}
- <if you ...>
- <when ...>
- <Before treatment with {product name},…>

<Taking><Using> other medicines
<Please tell your <doctor, health care provider><or><pharmacist> if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.>

<Taking><Using> {product name} with food and drink

Pregnancy and breast-feeding

<Ask your <doctor, health care provider><or><pharmacist> for advice before taking any medicine.>
Driving and using machines

<Do not drive <because...>.>
<Do not use any tools or machines.>

Important information about some of the ingredients of {product name}

c) HOW TO <TAKE><USE> {PRODUCT NAME}

<Always <take><use> {product name} exactly as your doctor or health care provider has told you. You should check with your <doctor, health care provider><or><pharmacist> if you are not sure.><The usual dose is...>

<Use in children>

If you <take><use> more {product name} than you should

If you forget to <take><use> {product name}

<Do not take a double dose to make up for a forgotten <tablet><dose><…>.>

If you stop <taking><using> {product name}

<If you have any further questions on the use of this product, ask your <doctor, health care provider><or><pharmacist>.>

d) POSSIBLE SIDE EFFECTS

Like all medicines, {product name} can cause side effects, although not everybody gets them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your <doctor, health care provider><or><pharmacist>.

e) HOW TO STORE {PRODUCT NAME}

Keep out of the reach and sight of children.

<Do not store above ºC>, <Store in the original <container><carton>>

Do not use {product name} after the expiry date which is stated on the <label><carton><bottle><...><after {abbreviation used for expiry date}.><The expiry date refers to the last day of that month.>
<Do not use {product name} if you notice {description of the visible signs of deterioration}.
<Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.>

f) FURTHER INFORMATION

What {product name} contains

- The active substance(s) is (are)…
- The other ingredient(s) is (are)...

What {product name} looks like and contents of the pack

Name and full physical address of Marketing Authorization Holderand Manufacturing site

{Name and address}
<{tel}>....<{fax}>.....<{e-mail}>
For any information about this medicinal product, please contact the <local representative of the> supplier:

{Country}	**{Country}**
{Name}	{Name}
<{Address}	<{Address}
B-0000 {City}>	B-0000 {City}>
tel: + {telephone number}.....<{e-mail}>	tel: + {telephone number} <{e-mail}>

<as appropriate, add additional local representatives to the above table>

This leaflet was last approved in {MM/YYYY}.

GN. No. 314 (contd.)

SECOND SCHEDULE

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH AND SOCIAL WELFARE

TANZANIA FOOD AND DRUGS AUTHORITY

CERTIFICATE OF MEDICINAL PRODUCT REGISTRATION

(Made under Regulation 12 (4) (c))

Registration number of the medicine

This is to certify that the medicine described below has been registered in Tanzania.

Trade name of the medicine

Name of the active ingredient(s) and strength

The form in which the medicine is presented and the colour thereof

Shelf life of medicine in months

Container-closure system(s) and pack size(s)

Storage statement

Distribution category

Name of marketing authorization holder

Name and address of the Manufacturer

Local Responsible Person

Issued on

Expires on

.....

GN. No. 314 (contd.)

(NAME)
DIRECTOR GENERAL

Conditions of registration

1. The medicine shall comply with all relevant provisions of the Tanzania Food Drugs and Cosmetics Act, Cap 219 and regulations made there under at all times.

2. Marketing authorization holder shall all time responsible for the quality and safety of the products circulated in the market.

3. The marketing authorization holder shall ensure that the medicines comply with Tanzanian labelling requirements at all times.

4. The marketing authorization holder shall ensure that the manufacturing facilities where a registered medicine is produced comply at all times with Tanzanian Good Manufacturing Practices requirements.

5. The marketing authorization holder and Local Responsible Person shall ensure that medicines within their control are stored and transported in accordance with the instructions and information provided in this certificate.

6. The marketing authorization holder shall ensure that application for renewal of registration is made 90 days before expiry of registration.

7. The marketing authorization holder shall ensure that retention fee is paid before 31st of January each year.

8. The Authority reserves the right to withdraw this certificate when conditions 1 to 7 are contravened and when the risks of the medicine outweighs the benefits or it is in public interest to do so.

9. The marketing authorization holder is duty bound to conduct periodic post-marketing surveillance and safety studies of registered medicines and report the outcome of such studies to the Authority.

Dar es Salaam,
10th May, 2015

SEIF SELEMAN RASHID
Minister for Health and Social Welfare