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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)(x),(z))

THE TANZANIA FOOD, DRUGS AND COSMETICS (RECALL, HANDLING AND DISPOSAL OF UNFIT MEDICINES AND COSMETICS) REGULATIONS, 2015

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PRELIMINARY PROVISIONS

Citation

1. These Regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Recall, Handling and Disposal of Unfit Medicines and Cosmetics) Regulations, 2015.

Application and Scope

2. These Regulations shall be used for recall, handling and disposal of unfit medicines and cosmetics and shall apply 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;

"Authority" means the Tanzania Food and Drugs Authority or its acronym "TFDA" established by section 4(1) of the Act;

"cosmetics" means any cosmetic substance or product as defined under the Act;

"disposal" means the process of rendering the unfit medicinal products or cosmetics for the duration of its biological and chemical activity such that it is harmless;

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"environmental inspector" means an inspector appointed under or designated pursuant to the section 82 of the Environmental Management Act;

"inspector" means an inspector appointed, authorized or recognized under the Act;

"importer" means person or institutions authorized under the Act to import medicinal products;

"Minister" means the Minister for the time being responsible for heath;

"medicinal product or medicine or 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, abnon-nal 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;

(c) disinfection in premises in which food and drugs are manufactured, prepared or kept, hospitals, equipment and farm houses; or

(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;

"recall" means the removal of specific batch or batches of a medicinal product or cosmetics from the market for reasons relating to deficiencies in the quality, safety or efficacy;

"superintendent" means a pharmacist in charge that supervises a pharmacy business and registered as such by the Pharmacy Council;

"unfit products" means medicinal products or cosmetics that are expired, improperly sealed, damaged, unexpired but improperly stored, improperly

labeled, counterfeit, substandard and adulterated, prohibited or unauthorized.

PART II
RECALL

Prohibition to sell products subjected to recall

4. No person shall sell, offer or expose for sale or supply medicinal products or cosmetics subjected to recall.

Product recall

5.-(1) The Authority on its own *suo moto* may, at any time when it is of the opinion that a medicinal product or cosmetic, for reasons relating to deficiencies in the quality, safety or efficacy, order recall of such product from the market at the cost of the manufacturer, registrant or importer as the case may be.

(2) On or before undertaking a recall referred to in sub regulation (1), the manufacturer, registrant or importer of a medicinal product or cosmetic shall provide the Authority with the following:-

(a) proprietary name and generic name, dosage form, strength, batch or lot number, pack size, the name and address of the manufacturer, manufacturing date and expiry date;

(b) the reason for the recall, the nature of the defectiveness or possible defectiveness, the date on and circumstances under which the defects or possible defects were discovered;

(c) the total quantity of the product being recalled originally in possession of the manufacturer, registrant or importer;

(d) the date on which distribution of the product began;

(e) the total quantity of the product being recalled that had been distributed up to the time of the recall;

(f) area of distribution of the product;

(g) list of customers to whom product was distributed; and

(h) the quantity of the recalled product still in possession of the manufacturer, registrant or importer.

(3) Notwithstanding the provision of sub regulation (1) the manufacturer, registrant or importer of a medicinal product or cosmetic may voluntarily initiate a recall of any medicinal product or cosmetic after receiving complaints from users or upon proof after investigation that such product has caused or is about to cause injury to the health or safety of patients, users or other persons.

(4) The manufacturer, registrant or importer of medicinal product or cosmetic who voluntarily initiate a recall under sub-regulation (3) shall be required to comply with the requirements stipulated under sub-regulation (1).

Report of recall

6.-(1) The manufacturer, registrant, or importer of a medicinal product or cosmetic shall submit to the Authority a weekly progress report of recall and the final report after completion of a recall which includes reconciliation between delivered and recovered quantities of the product.

(2) Subject to the provision of sub regulation (1), the manufacturer, registrant, or importer of a medicinal product or cosmetic shall submit to the Authority an investigation report detailing causes of the defect and corrective and preventive actions undertaken.

Health risk evaluation

7.-(1) An evaluation of the health risk presented by a product being recalled or considered for recall shall be conducted by the Authority and takes into account, but need not be limited to the following factors:

(a) whether any disease or injuries have already occurred from the use of the product;

(b) whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health risk. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health risk determination;

(c) assessment of risk to various segments of the population, e.g., children, surgical patients, pets, livestock, etc., who are expected to be exposed to the product being considered, with particular attention paid to the risk to those individuals who may be at greatest risk;

(d) assessment of the degree of seriousness of the health risk to which the populations at risk would be exposed;

(e) assessment of the likelihood of occurrence of the risk; and

(f) assessment of the consequences (immediate or long-range) of occurrence of the risk.

(2) Subject to sub-regulation (1), the Authority shall assign the recall a classification in the form of Class I, Class II, or Class III, to indicate the relative degree of health risk of the product being recalled or considered for recall.

Classification of recall

8.-(1) There shall be three classes of recall as provided in these Regulations depending on the nature of the health risk or adverse events.

(a) a Class I is for defective, dangerous or

potentially life threatening medicinal products or cosmetics that predictably or probably could result into serious health risk or adverse events or death;

(b) a Class II is for medicinal products or cosmetics that possibly could cause temporary or medically reversible adverse health problem or mistreatment; and

(c) a Class III is for medicinal products or cosmetics that are defective and are unlikely to cause any adverse health reaction or which do not comply with the requirements of the Act, in terms of the requirements of printed packaging material, product specification or labeling.

(2) The maximum time for recalling class I, II and III shall be fourteen, twenty one and thirty days respectively.

(3) Notwithstanding sub regulation (2), the Authority reserves the right to determine the maximum time for recall depending on the urgency and health risk involved.

PART III
HANDLING AND DISPOSAL OF UNFIT PRODUCTS

Restriction of disposal of unfit medicines and cosmetics

9. No person shall dispose off any unfit product unless he has requested the Authority and secured an approval to proceed with disposal procedure.

Decision to initiate disposal of unfit medicine

10. The decision to initiate disposal off unfit products shall be made by the Authority, Regional, District or Hospital Pharmacist, Owner or In-charge of facility or premises, Superintendent or an Inspector.

Request for disposal of unfit medicines and cosmetics

11.-(1) Request to dispose of unfit products shall be made to the Authority in Form TFDA D1 prescribed in the Schedule to these Regulations.

(2) A request shall be accompanied by a list of products to be disposed off which shall state clearly the trade name, generic name, strength and dosage form where applicable, type of packaging material, pack size, quantity, manufacturer, batch or lot number and market value of each product.

(3) Subject to the provision of sub regulations (1) and (2), request to dispose of unfit products from Government institutions shall be accompanied by an approval from Accountant General declaring that the products have been written off and that are subject to disposal as required by the Public Finance Act.

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Approval to dispose unfit medicines and cosmetics

12.-(1) The Authority shall, upon receipt of request for disposal, appoint an inspector to verify and authenticate the information submitted in relation to the consignment to be disposed.

(2) Verification referred to in sub regulation (1) shall be made in the Form TFDA D2 prescribed in the Schedule to these Regulations.

(3) The Authority after verification exercise shall inform the applicant to liaise with National Environment Management Council (NEMC) or any other institution responsible for environment management on the proposed mode of destruction and issuance of disposal permit.

(4) The applicant shall submit to the Authority disposal permit from NEMC, the applicant shall liaise with Local Government Authority for disposal site, cost and date of destruction.

(5) The cost of destruction shall be borne by the owner of the consignment.

Handling of unfit medicines and cosmetics

13.-(1) No person shall sell or supply or offer or expose for sale or supply or have in his possession for the purpose of sale or supply unfit products.

(2) Dealers of medicinal products and cosmetics shall adhere to the following requirements-

(a) maintain a register for unfit products as prescribed in Form TFDA D3 of the Schedule to these Regulations;

(b) keep separately medicines which fall under controlled drugs, antineoplastics, antibiotics and any other hazardous medicines or cosmetics;

(c) keep unfit products into different categories by dosage form such as-

(i) solids, semi semi-solids and powders: capsules, powders for injection, tablets, granules, creams, gels suppositories ;

(ii) liquids: solutions, suspension, syrups, mixtures, lotions, aerosol and inhalers,

(d) demarcate an area for keeping unfit products which shall be labeled conspicuously in red ink with words “Unfit for intended use” or “Hazifai kwa matumizi”;

(e) maintain safe custody of unfit products in registered premises until they are disposed.

Disposal of unfit medicines and cosmetics

14.-(1) Subject to any provision of these Regulations, an Inspector, Health Officer, environmental inspector, policeman and any other authorized officer shall supervise the transport of consignment from the premises to the disposal site for destruction exercise.

(2) The destruction exercise shall be supervised by Inspector, Health Officer, environmental inspector, policeman and any other authorized officer and upon

completion of the exercise a disposal Form TFDA D4 prescribed in the Schedule, shall be duly filled in and signed by the supervisors and the owner of the consignment or representative.

(3) The Authority shall upon receiving disposal form, issue a certificate of destruction of unfit products in Form TFDA D5 prescribed in the Schedule to these Regulations.

PART IV
GENERAL PROVISIONS

Offence

15. Any person who contravenes or fails to comply with any provision of these Regulations or who directly or indirectly aids another person in committing an offence under these Regulations commits an offence under the Act.

Penalty

16. Any person convicted of an offence under these Regulations shall be liable to the penalty prescribed by the Act.

FORMS

TFDA D1

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

REQUEST FORM FOR DISPOSAL OF UNFIT MEDICINE AND COSMETICS

(Made under Regulation 10(1))

I/We…….of (postal address)…… with premises registration number……of 20……..hereby apply for the disposal of unfit medicinal products/ cosmetics as per attached list.

Physical address of the Premises……..

Name of the superintendent/incharge……..Registration number (*if applicable*)……...

Reason(s) for disposal……

Weight (Kg)……..

Market value (in TZS)……..

Declaration:

I certify that the information provided in the application form is true and correct.

Date of application……..Signature of applicant……Stamp…….

For Official use only:

Received by……signature……..

Stamp……Date……..

TFDA D2

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

VERIFICATION FORM

(Made under Regulation 12(2))

Name of applicant…….of postal address……. undertaking the business of medicinal products or cosmetics as per attached list.

Physical address of the Premises ……

Weight (Kg)……..

Market value (in TZS)……

Does the actual product(s) tally with the list of product(s) submitted to TFDA? YES/NO

Other observation(s)……

Suggested mode of destruction……

Name of applicant…….Signature……

Date of verification……..

1. Name of Drug Inspector
……..Signature…….

2. Name of Drug Inspector ……Signature……

TFDA D2

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

REGISTER OF UNFIT MEDICINES AND COSMETICS

(Made under Regulation 13(2))

s/n	Date	Name of product		Strength (where applicable)	Dosage form	Pack size	Quantity	Batch No.	Value (TZS) where applicable	Reason for unfit	Date of disposal
		Trade Name	Generic Name								

TFDA D4

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

DISPOSAL FORM

(Made under Regulation 14(2))

The Tanzania Food and Drugs Authority declares to have supervised the disposal of unfit product(s) (as per attached list) belonging to M/S……of postal address……

The destruction exercise was conducted at (location, site) ……on this date …….. by the following method(s) (state clearly):-

1……

2……

3……

The total weight of the products destroyed is …..…Kgs and market value is ……. TZS

Name and signature of owner/representative of the organization:

……. …….

(Name) (Signature)

Names, titles and signatures of Inspector(s), other supervisor(s) and witness of the disposal exercise:-

Name: Title/Position: Signature & Date:

1……. ……. ……..

GN. No. 313(contd.)

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

TFDA D5

THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH AND SOCIAL WELFARE

CERTIFICATE OF DESTRUCTION

(Made under Regulation 14(3))

Ref. No:…….. **Date: ……..**

I, being the person in-charge with the administration of the law relating to the control of Products to which the Tanzania Food, Drugs and Cosmetics Act, Cap 219 apply, hereby certify the destruction of unfit Medicines/Cosmetics being the property of M/S**.....** of Postal Address ..... which took place on .....(date).

The said consignment was destroyed by ..... (method) at .....(location/site) under the witness and supervision of **Inspector, Environmental Officer, Health Officer and Police** as specified in the attached disposal form with S.No. **.....**

The weight of the consignment disposed was …….. Kg(s) and its market value was …… TZS.

..... **……**

Name of Director General **Signature**

Dar es Salaam **SEIF SELEMAN RASHID**
10th May 2015 *Minister for Health and Social Welfare*