DRUG REGULATORY PROCEDURES IN TANZANIA: A GLIMPSE

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REVIEW ARTICLE

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ABSTRACT

In Tanzania, Tanzania Food and Drugs Authority (TFDA), is a regulatory body responsible for controlling the quality, safety and effectiveness of food, drugs, herbal drugs, cosmetics and medical devices. The Authority has been ensuring safety, efficacy and quality of medicines by quality control tests; in addition to other quality assessment mechanisms. The guidelines laid by TFDA have also emanated from commitment to democracy and gives strong emphasis to the fulfilment of the needs of the less privileged rural population.
Tanzania is an emerging market; the pharmaceutical market is valued at over US$250 million, and is growing at an annual rate of around 16.5% and is expected to reach approximately US$550 billion in 2020. Currently, the market is highly dependent on imports, which account for around 75% of the total pharmaceutical market.

The procedures and approval requirements of new drugs, variations, import, export and disposal have been set up by the TFDA, which help in maintaining quality of the drug products that are imported as well being produced locally

Keywords: Tanzania, TFDA, New drug, Disposal, Import, Export and Variation.

INTRODUCTION

Tanzania, officially the United Republic of Tanzania is a country in East Africa in the African Great Lakes region. Drugs in Tanzania are under the control of Tanzania Food and Drugs Authority(TFDA). This work gives a glimpse of various applications and other requirements for drug approval in Tanzania.

Overview of Regulatory Authority

In Tanzania, TFDA is a regulatory body responsible for controlling the quality, safety and effectiveness of food, drugs, herbal drugs, cosmetics and medical devices. It is established under Tanzania Food, Drugs and Cosmetics Act No. 1 of 2003, after repealing the Pharmaceutical and Poisons Act No. 9 of 1978 (which established the Pharmacy Board) and Food {Control of Quality} Act No. 10 of 1978 (which established the National Food Control Commission). (1) The current guidelines are the latest were published in August 2012 and released in October 2012 which is the 5th edition (TFDA/DMC/MCER/G/001) of the guidelines in accordance with the Tanzania Food, Drugs and Cosmetics Act, 2003.

DRUG REGISTRATION APPLICATIONS

An application consists of documentation in hard copies and electronic form, samples and fees. Applications are classified into 4 categories as follows

1. New Application
2. Application for Variation of a registered medicinal product
3. Application for importation and exportation of pharmaceutical products
4. Application for safe disposal of unfit medicines and cosmetics products

1. New Application (2)

This is given for registration of any new product in Tanzania.

Registration requirements:

a. Pre-Registration Requirements:

- Identification of a local person in Tanzania or a company incorporated in Tanzania and authorized by TFDA to deal in medicinal products

- Power of attorney that complies with Tanzanian laws.

- GMP (Good Manufacturing Practices) inspection by TFDA

b. Registration requirements

Section 1: General Information

- Application Form
  - Quality Information Summary
  - Bioequivalence Information Summary
- Table of contents
- Certificate of Pharmaceutical Product
- Site Master File

Section 2: Summary of Product Characteristics

Section 3: Active Pharmaceutical Ingredient (s)(API)

This section also include documents like

- CEP (Certificate of Suitability to the monographs of the European Pharmacopoeia) + sections not covered in CEP or
- DMF (Drug Master File); or
- Declaration by the API manufacturer

Section 4: Finished Pharmaceutical Product(s) (FPP)

Section 5: Therapeutic equivalence

Section 6: Pharmacology, toxicology and efficacy of new products

Section 7: Fixed dose combination medicinal products

Evaluation Process:

Evaluation is done on a first-in-first-out (FIFO) basis unless the product meets the fast track criteria. Assessment involves evaluators from within or outside TFDA. The report produced by the evaluator is reviewed by 2nd senior evaluator/s who does the quality assurance of the report & finalizes the report & recommendations. A summary of recommendations of evaluation, lab analysis & GMP status reports is presented before the Human Medicines Registration Technical Committee (HMRTC) for consideration & making final recommendations for granting or rejecting registration of the product. Process of evaluation has been summarized in Figure 1.

Timelines

a. Evaluation of New Applications: Complete applications are evaluated within 180 working days of receiving the application including evaluation of documentation and consideration by a technical committee.

b. Fast-Track Evaluation: An application may be fast tracked & be evaluated within six months of its submission, if the applicant has requested & paid twice the prescribed evaluation fees and the product is lifesaving, or the product is indicated for diseases which at the time of application have no registered alternative medicine or evidence has been submitted in a motivation letter accompanying the application to show that the product has significant advantages in terms of safety and efficacy over existing products indicated for treatment or prevention of life threatening diseases.

Validity of registration

The registration of a human medicinal product is valid for five (5) years unless earlier suspended or revoked by TFDA or withdrawn by applicant.

2. Application for variation of a registered medicinal product (3)

Any changes to registered products (variations) may involve administrative and / or more substantial changes and are subject to approval by TFDA. Procedures for the implementation of the different types of variations need to be set out in order to facilitate the task of both Marketing Authorization Holders and TFDA and to guarantee that variations to the medicinal product do not give rise to public health concerns.

3. Application for Importation and Exportation of Pharmaceutical Products (4)

Importation of pharmaceutical products and raw materials

- Categories of importers of pharmaceutical products and raw materials

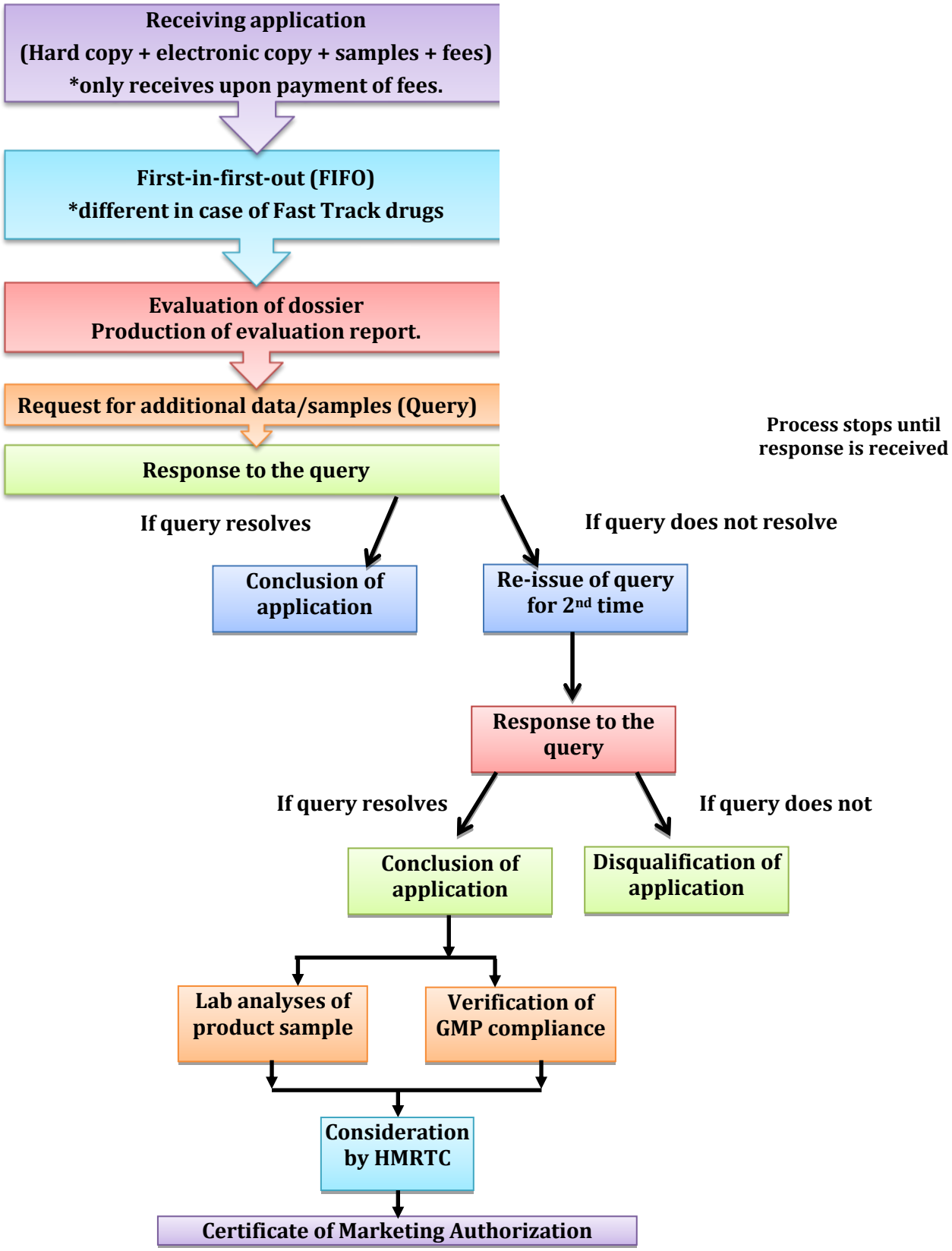

Figure 1: Evaluation Process of drug application

Importers of pharmaceuticals shall fall under the following categories:

a) Government and Non-governmental institutions
b) Pharmaceutical wholesalers
c) Pharmaceutical manufacturers
d) Clinical trial sponsors and principal investigators
e) Recipients of donations

However, the following in the special circumstance can be authorized

a) Persons authorized to import pharmaceuticals for personal use
b) Hospitals authorized to import pharmaceuticals for hospital use

Requirements for importers

a) All pharmaceutical products to be imported must be registered by TFDA unless given special approval by the Authority.

b) All importation of pharmaceutical products must be done by importers whose premises are dully registered by TFDA or relevant Government institution.

c) All importers must import pharmaceutical products through the authorized POE (Port of Entry).

d) In case of donations, importer must have a donation certificate and adhere to the *Guidelines for Donations*. The donated pharmaceutical products must be fit for human consumption, safe and of good quality and not prohibited in the country of origin.

e) No person shall import any pharmaceutical product with shelf life of more than 24 months whose remaining shelf life is less than 60% and a drug with shelf life of less or equal to 24 months whose remaining shelf life is less than 80%.

f) All imported pharmaceutical products should adhere to the following labeling requirements:

- The information printed on labels must be indelible, engraved or embossed on a primary and secondary container.
- The immediate outer packaging of the pharmaceutical products should be clearly labeled in English or Swahili language or both
- The trade or brand name where appropriate shall be stated
- The International Non-proprietary Name (INN, Generic name) shall be clearly stated
- Quantities of active ingredients in the given formulation / API
- Date of manufacture and expiry
- Batch or Lot number
- Storage conditions
- Name and address of manufacturer
- Registration number of the product issued by TFDA in both outer and inner package of the product(s) where applicable
- Enclosed and accompanying literature must be in English or Swahili language.
- API specification (BP, USP, etc)

Exportation of Pharmaceutical Products and Raw Materials

A. Exporters of pharmaceutical products

Exporters of pharmaceuticals fall under the following categories

i. Registered local pharmaceutical manufacturers
ii. Registered wholesalers
iii. Clinical trial sponsors and investigators
iv. Person authorized by TFDA

B. Requirements for exporters

i. No person shall export pharmaceutical products out of the country without having a valid export permit issued by the Authority
ii. All pharmaceutical products to be exported must come from a registered manufacturer or

wholesale pharmacy in Tanzania Mainland

iii. All exporters must export pharmaceutical products through the authorized PoE

4. Application for safe disposal of unfit medicines and cosmetics products (5)

For quite a long time, disposal of unfit medicines and cosmetic products in Tanzania was not been done systematically and professionally due to lack of appropriate guidance which resulted to accumulation of unfit medicines and cosmetic products in drug outlets in the country. The accumulation of these products has been mainly contributed by lack of adequate knowledge on procedure for safe disposal of unfit medicines and cosmetics products among the dealers.

In order to protect the entire Tanzanian population, medicines and cosmetics manufacturers, dealers, private health facilities and institutions, Local Authorities, Non-Governmental Organizations (NGOs), drug inspectors and the general public are required to adhere to set procedures as stipulated in these guidelines.

TFDA has developed the guidelines to provide guidance to medicines and cosmetics dealers on how to dispose off medicines and cosmetic products safely. The guidelines have been developed in line with the current development in science and technology of medicines and cosmetics formulations based on the World Health Organization (WHO*) Guidelines for safe disposal of unwanted pharmaceuticals in and after emergencies.*

Procedures for application to dispose off unfit medicines and cosmetic products

Any person who intends to dispose off unfit medicines or cosmetic products shall adhere to the following procedures:

i. Request in writing to the Director General of TFDA by using application form which is available at TFDA headquarter offices, TFDA zone offices, Regional and District Medical officer's offices and TFDA website: www.tfda.ac.tz.

ii. A request shall be accompanied with a list of products to be disposed of and should state clearly trade name, generic name and strength (where applicable), dosage form, pack size, quantity, manufacturer, batch number and market value of product.

iii. Once the request has been received by TFDA, the Authority shall acknowledge and inform the applicant through a letter to contact Directorate of Medicines and Cosmetics to arrange or TFDA zone offices for verification of the product. In case of regions where there are no TFDA zone offices, applicant shall be informed to contact the Regional or District Medical officer's offices for the same.

iv. TFDA-HQ or TFDA zone office / Regional / District Medical officer's offices shall send inspectors to the premises to verify and authenticate the information submitted.

Various disposal methods for different categories have been summarized in Table 1.

Table 1: Various categories of products and their disposal methods

Sl. No.	Category	Disposal methods
1.	Solids, semi-solids and Powders	Landfill, incineration and waste Immobilization
2.	Liquids	Sewer, high temperature incineration and treated waste
3.	Antineoplastics	Treated waste and landfill, high temperature incineration and return to manufacturer

4.	Controlled drugs	Treated waste and landfill, high temperature incineration
5.	Aerosols and inhalers	Landfill without waste inertization
6.	Disinfectants	Sewer or fast-flowing watercourse
7.	PVC plastics, glass (ampoules, bottles and vials)	Landfill and re-cycling
8.	Paper, cardboard	Recycle, burn, landfill

Destruction of Unfit Medicines and Cosmetic Products

Destruction of unfit medicines and cosmetic products shall involve the following procedures:

A. A Drug Inspector, Health Officer, Environmental Officer and Policeman shall supervise the transport of consignment from the owner's premises to the disposal site for destruction exercise.

B. The destruction exercise shall be supervised by Health Officer, Environmental Officer, Policeman and Drug Inspector.

C. Unfit medicines and cosmetic products shall be transported in a closed motor vehicle to avoid pilferage.

D. Supervisors shall wear protective gears such as overalls, gloves, masks, caps and boots during the exercise.

E. Upon completion of the exercise, a Drug Disposal Form shall be duly filled in and signed by the supervisors and owner/owner's representative.

F. Drug Disposal Form shall be sent to TFDA headquarter offices.

G. Once TFDA has received the form, a certificate of destruction of unfit medicines and cosmetic products shall be prepared and sent to the consignee.

H. Particular care shall be taken while handling anti-cancer drugs, narcotic drugs and Penicillins to avoid associated hazards.

Fees (6)

As per the TFDA regulations, applicant has to pay fees depending on the type of certification applied for. Various services provided by TFDA along with fees has been summarized in Table 2.

Table 2: Fees for application in Tanzania

Sl. No.	Service	Cost
1.	Registration of medicinal products	A. Locally manufactured medicinal products: • Registration Fees : TZS 600,000 • Variation : TZS 60,000 • Retention : TZS 100,000 • Duplicate Certificate : TZS30,000 B. Both old and new foreign medicinal products • Registration Fees : USD 1,250 • Variation o Major : USD200 o Minor : USD100 • Retention : USD200 • Duplicate Certificate : USD30
2.	Fast track for medicinal products registration	• Double the cost of registration

3.	GMP Inspection within specified period of product registration	• Local pharmaceutical facilities : TZS 150,00 per year • Overseas Pharmaceutical facilities ○ East Africa : USD3,000 ○ Africa : USD4,500 ○ Far East and Asia / India : USD 6,000 ○ Europe and America : USD 6,500
4.	Certificate of Pharmaceutical Product(CPP)	• TZS 20,000
5.	Disposal Certificate	• TZS 30,000
6.	Export Permit for all regulated product	• TZS 20,000
7.	Permit for Psychotropic and Narcotics drugs	• TZS 20,000

CONCLUSION

Tanzania presents a highly regulated business environment and more specifically, strict regulations within the pharmaceutical market pose many challenges. The pharmaceutical products like drugs for human use (New and generics) have well defined guidelines among all pharmaceutical products and the application for registration must be compiled in a specified format as mentioned in guideline, "*Guidelines on Submission of Documentation for Registration of Human Medicinal Products*". Well organized and compiled documents will facilitate the evaluation process and decrease the screening time.The study points towards a positive trend stating that despite prevailing challenges, the market for pharmaceutical products is likely to remain strong in the wake of lifestyle changes region-wide. The prospects for the sector are likely to improve over time as local and national legislation continues to be in closer agreement with international standards. Growing population and incomes underpin the growth-dynamic for the foreseeable future.

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CONFLICT OF INTEREST

Author declares that there are no conflicts of interest.

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