PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

(Set up by Ministry of Commerce & Industry, Govt. of India)

REGULATORY & MARKET PROFILE OF TANZANIA

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	Africa
2	Country	United Republic of Tanzania
3	Capital	Darussalam
4	Population	55,451.343 (July 2018 est)
5	Population growth rate (%)	2.74%(2018est)
6	GDP (purchasing power parity)	$ 162.5 Billion (2017est.)
7	GDP - real growth rate (%)	6 % (2017 est.)
8	GDP - per capita (PPP)	$ 3,200(2017 est.)
9	Epidemiology	Malaria, HIV/AIDs and Tuberculosis
10	Population below poverty line	22.8%(2015 Estimate) (No update)
11	Age structure (%)	0-14 years: 43.4%
		15-24 years: 20.03%
		25-54 years: 30.02%
		55-65 years : 3.51%
		65 & above: 3.04%
Source: CIA World Fact Book updated till July 2018		

TANZANIA- PHARMA MARKET REPORT

Introduction:

Tanzanian pharmaceutical market is likely experience robust growth in the coming years, and might l remain a less preferred destination for top MNcs. The market is limited by low per capita spending on medicines and an underdeveloped healthcare sector. Whilst demand for medicine will increase over the long-term, driven by the country's rapidly expanding population and high disease burden, Tanzania's pharmaceutical sector is likely to remain dominated by generic drug makers, with a majority coming from India.

Market was worth around $496 million in 2017 and is expected to touch $ 538 million in 2018 with a growth of 8.3 % .

Updates

In August 2018, Tanzania Medical Stores Department (MSD) announced it was delaying the supply of essential drugs and equipment to the Southern African Development Community (SADC) – of which it was appointed as the sole distributor – until the ICT platform becomes fully harmonised across the 15-member states, estimated for next year.

In August 2018, Health Minister Ummy Ali Mwalimu welcomed more Chinese investment at a high-level China-Africa health cooperation meeting, highlighting that China accounted for one quarter of all pharmaceutical imports in 2017 and was responsible for greater access to medicine at a lower price.

In August 2018, the government decentralised Tuberculosis (TB) healthcare services to local authorities so to reduce inconveniences of covering long distances by people to health centres.

In an interview with the Daily Trust in August 2018, Tanzanian High Commissioner to Nigeria, Muhidini Ally Mboweto, highlighted the several new incentives available to Nigerian investors, among which is zero percent import duty for manufacturing pharmaceutical products.

Healthcare sector stakeholders and government officials are to meet at the 5th Tanzanian Health summit in November 2018, focused on healthcare industrialisation, a major component towards achievement of sustainable development goals in line with the Tanzania Vision 2025

Strengths:

- Tanzania's pharmaceutical expenditure fares well against comparable countries in Sub-Saharan Africa (SSA).
- The pharmaceuticals market in Tanzania is forecast to grow strongly over the next few years, largely due to an increasing disease burden.
- The government's interest in developing the pharmaceutical sector.
- High rate of population growth and urbanisation will continue to support pharmaceutical market growth, creating revenue earning opportunities for drug makers.

Weaknesses

- Underdeveloped but improving pharmaceutical procurement and distribution system, plagued by financial problems.
- Limited public healthcare provision and staff shortages.

- Many Tanzanians lack access to health facilities due to financial reasons or because of sparse healthcare infrastructure in rural areas.

Opportunities

- Progress has been made towards establishing the East African Medicines and Food Safety Commission, which if successful, would improve drug registration processes.
- Good scope to associate with local companies for manufacturing (re-packing is also considered as manufacturing) this would help addressing sub-saharan markets.
- Large and increasing burden of disease suggests a significant unmet demand for pharmaceuticals.
- Programme to introduce a national health insurance scheme will improve access to medicines in the longer term.
- Tanzania has the largest proportion of the working age population in employment in SSA, meaning that uptake of the national health insurance scheme will occur faster many of its regional peers.
- Self-medication is prevalent in Tanzania, making the OTC medicine market an attractive prospect.

Market Overview

Tanzania's pharmaceutical market is among the largest in Sub-Saharan Africa. Tanzania's pharmaceutical market is valued at USD 496 mn, with per-capita drug expenditure at just over USD 8.7 in 2017. Forecast show that it would reach $730 million by 2022 with cagr of 8%.

This is fairly modest in global terms and even by regional standards. Due to low purchasing power, generic drugs comprise the majority of Tanzania's pharmaceuticals market, providing opportunities for companies focused on off-patent drugs. Patented drugs only hold a small market share as low per-capita drug expenditure continues to limit the capacity of most of the population to purchase the higher-priced. Self-medication is prevalent in Tanzania, making the OTC medicine market an attractive prospect. As such, Indian drug makers will be especially well placed to gain a foothold in the Tanzanian market given their drug makers' cost-competitiveness.

In April 2018, the Ministry of Health, with the Ministry of Industry Trade and Investment, met with Tanzanian health sector stakeholders to urge the investment in the local industries as to reduce its dependency on imported medical supplies and pharmaceuticals. This was followed by an announcement in May 2018, that the ministries of Industry, Trade and Investment and Health set a five-year target to produce 50% of hospital drugs and medical equipment locally as well as reducing the cost of domestically procured medicine.

Pharmaceutical Trade forecast:

Though the government is making efforts to reduce its reliance on imports, rapid increase in the cost of imports due to its currency fluctuation and also its needs increasing at a faster pace than the efforts, Tanzania' may remain import dependent for some more years. With regards to imports, it is forecasted an increase from USD 325.7 mn In 2017 to USD424 mn in 2022 – with a Cagr of5.4%.

According to UN Comtrade data, Tanzania imports the majority of its medicines from India, Kenya and the US - these three countries accounted for over 80% of the market in 2016. Imports from India was $168 million in 2016. The government of Tanzania has previously encouraged Indian generic drug makers to establish production facilities locally.

The region of Zanzibar is offering five-10 year tax breaks for Indian pharmaceutical companies in this respect. Cadila, Hetero Labs, Cipla, Ajanta Pharma, Ranbaxy and Dr Reddy's Laboratories, among others, all supply products indirectly to the country.

The depreciating Tanzanian shilling and in turn, the increasing prices of imported raw materials will continue to limit domestic pharmaceutical production and thereby increases import of Finished dosage forms especially generics from bases like India.

Regulatory Developments

In November 2017, the TFDA launched 10 minilab kits that will be used to strengthen its Quality Assurance Programme for rapid medicine quality verification and counterfeit medicines detection in the field. The Quality Assurance Programme started in 2002 and began with five minilab kits with support from the WHO and screens around 1,485 samples annually. According to the TFDA, the programme has been successful in reducing substandard and counterfeit medicines in circulation, from 3.7% in 2005 down to less than 1.0% in 2017.

Epidemiology

The burden of both communicable and non-communicable diseases remains high in Tanzania, and the expectations are both would persist over the long-term. Communicable diseases inflict a greater burden, with malaria, HIV/AIDs and tuberculosis acting as significant health concerns. As Tanazania is a less developed increase in longevity of the population is not likely to alter the disease pattern and communicable diseases persist at higher percentage even in this aged population.

UNAIDS estimates that 1.4mn Tanzanians are living with HIV, equating to a prevalence rate of 4.7% among adults aged between 15 and 49. The Global Fund To Fight AIDS, Tuberculosis and Malaria estimates that only 69% of these sufferers aged over 15 are receiving antiretroviral (ARV) therapy, despite the government providing ARV drugs free of charge to all HIV sufferers since 2003.
While malaria cases have declined, the disease still poses a severe burden in Tanzania . Malaria is the fourth leading cause of death in the country, representing 5.2% of deaths according to the World Health Organization (WHO).

There are around 8,23, 000 persons with diabetes in Tanzania

INDUSTRY in the Country

The government clearly realizes the importance of achieving self-sufficiency in terms of pharmaceutical production, and has encouraged investments from Indian generic drug makers to establish production facilities locally; the semi-autonomous region of Zanzibar is offering 5-10 year tax holidays for Indian pharmaceutical companies in this respect. Tanzanian authorities have reportedly been seeking collaborations with international pharmaceutical companies to promote the local development of medicines.

According to the Tanzania Food and Drugs Authority there are seven registered pharmaceuticals manufacturers in Tanzania: Tanzania Pharmaceuticals Industries, AA Pharmaceuticals, Keko Pharmaceuticals, Mansoor Daya Chemical, Shelys Pharmaceuticals (which entered into a long-term strategic partnership with South African drugmaker Aspen in 2008), Tanzansino United Pharmaceuticals and Interchem Pharmaceuticals. Multinational drugmakers such as GlaxoSmithKline, AstraZeneca, Sanofi, Johnson & Johnson, Boehringer Ingelheim, Bayer, Novartis and Novo Nordisk supply the market via exports. Indian drugmakers including Ranbaxy, Dr Reddy's, Cipla, Strides Arcolab, Panacea Biotech and Piramal Healthcare also supply the sector, primarily through the import of generic medicines.

In 2009, it was estimated that 33% of the requirement of medicines were produced locally. in 2016, it is estimated that local manufacturers' public and private market share stands at 10-20%. Continued registration delays, unfavourable tax laws, labour shortages, rising operational costs due to poor infrastructure and rising power prices have all contributed to this drop.

The Tanzanian government clearly realizes the importance of achieving greater self-sufficiency in terms of pharmaceutical production and has taken steps to realise this. In November 2016, a collective of six foreign investors expressed an interest in Tanzania's pharmaceutical sector: JNS Solution, Boryung Pharmaceuticals, Zinga Pharmaceuticals, China Dalian International Economic Development Group, Aga Khan Foundation Network and Hainan Hualon. According to Charles Mwijage, Tanzania's Trade and Investments Minister, the government has tasked a number of public institutions to create a more conducive investment environment in the pharmaceutical sector, including the Medical Stores Department (MSD), National Health Insurance Fund (NHIF), Tanzania Investment Bank (TIB), Tanzania Food and Drugs Authority (TFDA) and Tanzania Industrial Research and Development Organisation (TIRDO).

A WHO Study highlights that viability of local pharmaceuticals production in Tanzania, may not compare with more cost-effective imported drugs from India (which is home to more than 70 US-approved production plants where APIs and ARVs can be produced).

Opportunities in Government Financed & Donor Funded Healthcare Sector

All pharmaceuticals producers can participate in pharmaceuticals tenders issued by the government. Local producers enjoy 15% preferential treatment and have to comply with Tanzanian good manufacturing practice standards. Highlighting further opportunities for companies, donor funding accounts for a large proportion of healthcare finances in Tanzania and if local producers of drugs comply with international quality standards they can participate in tenders issued by the donor community in the country (and the region) - thereby gaining increased access to the ARV pharmaceuticals market in Tanzania.

Sources of donor funds for ARV procurement in Tanzania include multilateral partners (such as NORAD, the Norwegian Agency for Development Co-operation), bilateral partners (such as UNITAID, the international facility for the purchase of drugs against HIV/AIDS, Malaria and Tuberculosis), NGO partners (such as AXIOS, an international philanthropic organisation) and private partners (such as Crown Agents, a global procurement agent).

Statistics:

India's Pharmaceutical exports to TANZANIA REP $ Million						
Category	**2015-16**	**2016-17**	**2017-18**	**GR%**	**Contbn %**	**Contbn to Region**
Bulk drugs and Drug intermediates	4.54	4.86	8.40	72.82	4.52	2.14
Drug Formulations and Biologicals	162.99	173.50	166.80	-3.86	89.72	6.44
Ayush	0.43	0.47	0.56	19.35	0.30	3.15
Herbal Products	0.02	0.03	0.04	26.36	0.02	1.29
Surgicals	1.79	2.20	2.47	12.25	1.33	5.10
Vaccines	9.03	15.16	7.64	-49.63	4.11	2.59
Total	178.80	196.22	185.91	-5.26	100.00	5.55

Imports of Tanzania

Top Ten Importing Partners of United Rep. of Tanzania $ Million						
Rank	**Country**	**2015**	**2016**	**2017**	**Gr%**	**Share%**
1	India	155.41	167.69	251.84	50.18	59.19
2	Denmark	54.61	29.50	29.73	0.78	6.99
3	Kenya	25.84	49.74	23.50	-52.76	5.52
4	Germany	2.45	4.22	23.38	454.43	5.50
5	China	12.80	13.18	21.11	60.17	4.96
6	Netherlands	18.88	8.81	13.06	48.29	3.07
7	Belgium	4.05	16.30	9.09	-44.21	2.14
8	USA	93.15	4.34	7.08	63.02	1.66
9	Rep. of Korea	0.93	1.07	5.26	390.53	1.24
10	France	1.67	3.42	5.21	52.40	1.22
World		402.87	329.32	425.45	29.19	100.00

REGISTRATION AND LICENSING REQUIREMENTS

➢	Regulatory Authority	:	**Tanzania Food and Drugs Authority (TFDA)**
➢	Website of regulatory Authority	:	https://www.tfda.go.tz/
➢	Fees for Drug Registration	:	2000 USD for Normal Registration 4000 USD for Fast Track Registration 6000 USD for GMP Inspection (For Asia) Annual retention Fee- 300 USD
➢	Normal time taken for registration	:	12 Months (Normal) 06 Months (Fast Track)
➢	Registration Requirement [Dossier Format]	:	CTD
➢	Whether plant inspection is mandatory	:	YES
➢	Requirement of Local agent/ Subsidiary		Local Agent is sufficient
➢	Registration Validity		05 Yrs, subject to payment of annual Retention fee of 300USD

Tanzania Food and Drugs Authority (TFDA)

Tanzania Food and Drugs Authority (TFDA) is an Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGE). TFDA is responsible for regulating safety, quality and effectiveness of food, medicines, cosmetics, medical devices and diagnostics.

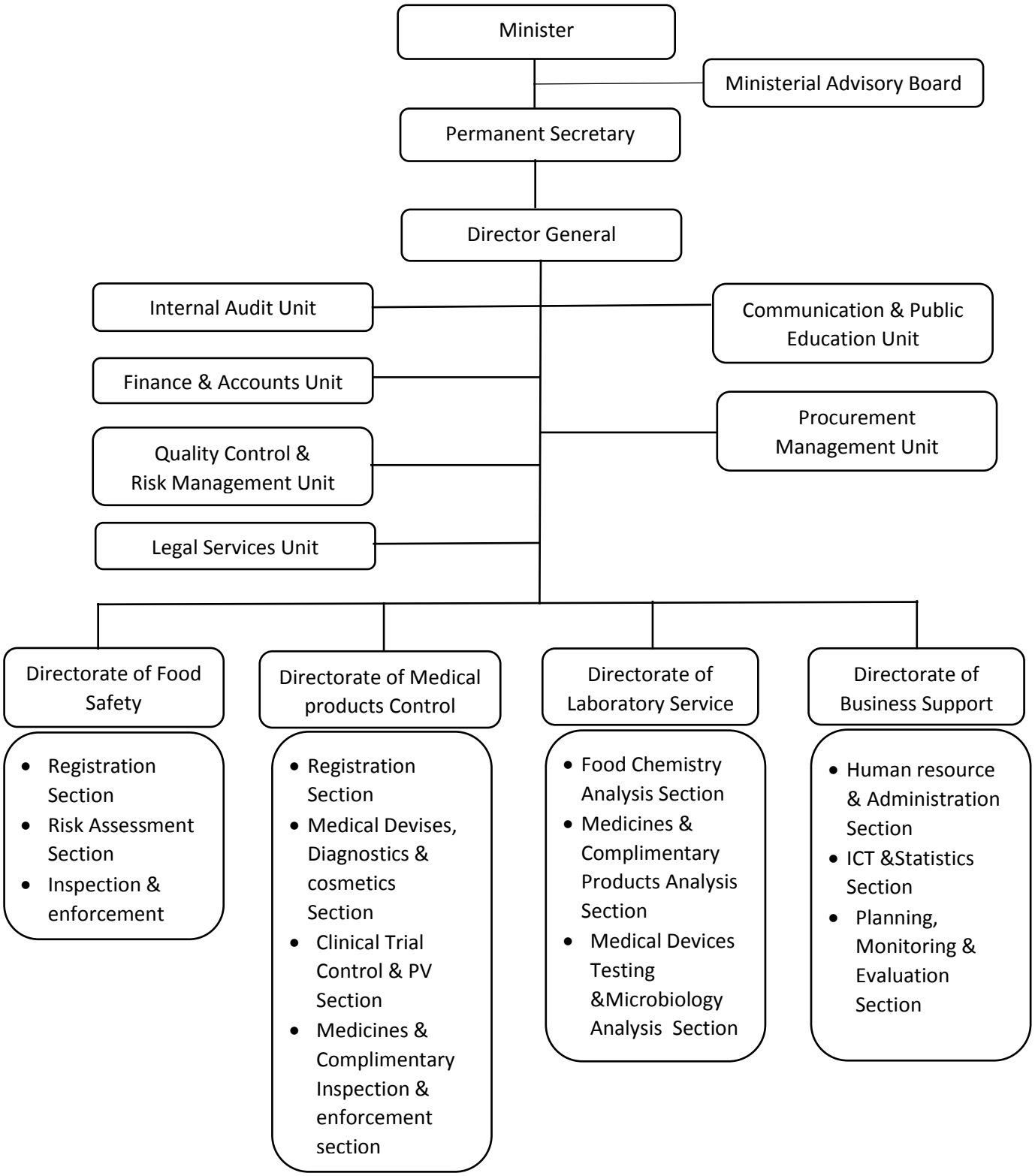
VISION

To be the leading Regulatory Authority in ensuring safety, quality and effectiveness of food, medicines, cosmetics, medical devices and diagnostics in Africa.

MISSION

To protect and promote public health by ensuring safety, quality and effectiveness of food, medicines, cosmetics, medical devices and diagnostics.

TFDA Organogram



QUALITY POLICY STATEMENT

TFDA is committed to provide quality services in response to customer needs and expectations. TFDA shall strive to balance the interests of our stakeholders without compromising quality, safety and effectiveness of food, medicines, cosmetics, medical devices and diagnostics by managing the Authority with utmost professionalism.

TFDA is committed to comply with the requirements of ISO 9001:2015 Standards and continually improve effectiveness of Quality Management System (QMS). It shall manage and provide resources for continuous improvement of our services to ensure customers' satisfaction."

ACT: THE TANZANIA FOOD, DRUGS AND COSMETICS ACT, 2003

REGISTRATION OF MEDICINAL PRODUCTS

- 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 (Given below)

  (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 fil**e 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.

- A separate and complete application for registration of medicinal products shall be submitted for each medicinal product.

- 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.

- All parenteral preparations in different pack sizes shall require separate applications

Data requirements:

One can refer to the GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR REGISTRATION OF HUMAN PHARMACEUTICAL PRODUCTS for submitting the dossier.

Dossier Format: CTD

The 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.

m) For New medicinal products with use in paediatric population: All applications for registration of new medicinal products intended for use in paediatric population shall be accompanied by a Paediatric Investigation Plan (PIP).

- When Authority requires additional samples, documents, information, data and or clarification, applicant shall submit the requisite information within the period of six months from the date of request letter, otherwise the application shall be rendered withdrawn.

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

- 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.

- 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.

- 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

- Approval issued for provisional registration will specify the conditions which need to be fulfilled by marketing authorization holder to acquire full registration.

Validity of Registration:

- A certificate of full registration issued is valid for a period of five years from the date of issuance subject to payment of prescribed annual retention fees before 31st January of each calendar Year and thereafter may be renewed.

- A certificate of provisional registration shall be valid for a period specified in the certificate and that period shall not exceed three years.

Application for renewal of registration:

GUIDELINES ON SUBMISSION OF DOCUMENTATION FOR RENEWAL OF REGISTRATION OF HUMAN AND VETERINARY PHARMACEUTICAL PRODUCTS

- 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.
- A grace period for renewal shall extend to ninety days after the specified expiry date.
- 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) Nonrefundable application fees as prescribed in the Fees and Charges Regulations in force; and
f) Nonrefundable 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.

APPLICATION GUIDELINES FOR VARIATION OF REGISTERED HUMAN MEDICINAL PRODUCTS

As per the guidelines, four schedules which define the various types of changes are delineated:

Schedule I: Lists minor changes (Dossier requirements for minor changes to registered medicinal products). These are classified by the type of change as such and the conditions which

frame this type of change. Whenever the conditions are not kept, the change may either become a major change or may even make a new application necessary.

Schedule II: Lists examples of major changes.

Schedule III: Lists types of changes which make a new application necessary.

Schedule IV: Lists stability requirements for variations and changes to registered finished pharmaceutical products (FPPs)

SCHEDULE II: MAJOR CHANGES (EXAMPLES):

1. Change or addition of a manufacturing site of finished product
2. Change in the manufacturing process of the API
3. Change in the composition of the finished product
4. Change of immediate packaging of the product

SCHEDULE III: CHANGES THAT MAKE A NEW APPLICATION/ EXTENSION APPLICATION NECESSARY

1.Change or addition of a manufacturing site of finished product
2.Changes to the API
3.Changes to the pharmaceutical form/dosage form
4.Changes in the route of administration

SCHEDULE IV: STABILITY REQUIREMENTS FOR VARIATIONS AND CHANGES TO REGISTERED FINISHED PHARMACEUTICAL PRODUCTS (FPPs)

For APIs:

1. The stability profile including the results on stress testing.
2. The supportive data.
3. The primary data of accelerated and long-term testing.

For FPPs:

1. The supportive data.
2. The primary data of accelerated and long-term testing.

THE TANZANIA FOOD, DRUGS AND COSMETICS (FEES AND CHARGES) REGULATIONS, 2015

TFDA Fees and charges structure

REGISTRATION/RETENTION/NOTIFICATION/VARIATION

Human, Veterinary Medicines and Biologicals (Imported)		
01	Registration	2,000 USD
02	Registration – biological	3,500 USD
03	Retention	300 USD
04	Variation – Major	1,000 USD
05	Variation – Minor	300 USD
06	Duplicate certificate	100 USD
07	Fast track registration-Pharmaceuticals	Double the respective fee
GMP inspection fee per block (Foreign)- Asia – 6000 USD		

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*

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

(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.