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PHARMACEUTICAL REGULATION IN TANZANIA:

BALANCING INNOVATION AND SAFETY

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INTRODUCTION

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Tanzania is the promising investment destinations, supported by strong economic reforms, political stability, and a rapidly growing consumer market that continues to attract investors across multiple sectors. A key driver of this opportunity is its expanding population base, which directly shapes demand for goods, services, and industrial growth. This is further strengthened by a well-structured regulatory environment, supported by strong institutions such as, Tanzania Medicines and Devices Authority (TMDA), Business Registration and Licensing Agency (BRELA), Tanzania Investment and Special Economic Zones Authority (TISEZA), Tanzania Revenue Authority (TRA) and Local Government Authorities, which ensure a clear, reliable, and investors friendly framework for doing business in Tanzania.

Population Growth

The 2022 Population and Housing Census results show that the population has increased from 44,928,923 recorded in 2012 to 61,741,120 in 2022, equivalent to an annual intercensal population growth rate of 3.2 percent. This significant population growth positions the country to the fastest-growing markets in East Africa, creating opportunities for investors across multiple sectors.

For Mainland, the population increased from 43,625,354 in 2012 to 59,851,347 in 2022, demonstrating a rapidly expanding demand for housing, commerce, infrastructure, healthcare, education, transportation, technology, and consumer goods.

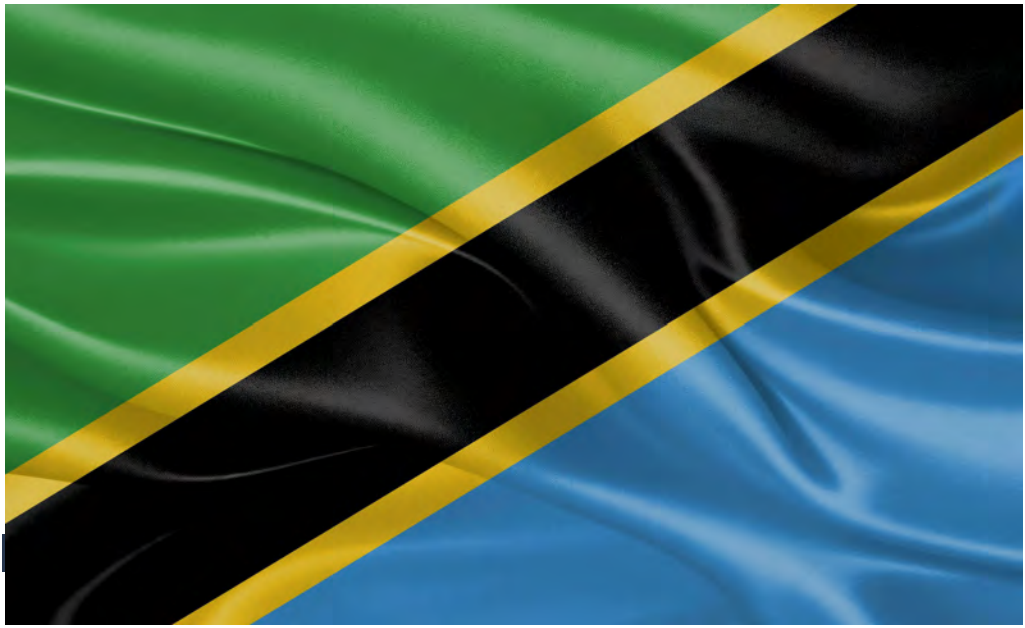
For Tanzania Zanzibar, the population increased from 1,303,569 in 2012 to 1,889,773 in 2022, reflecting continuous market expansion and emerging investment opportunities in tourism, trade, services, and social development.

Out of the 61,741,120 people counted in 2022 in the United Republic of Tanzania, 30,053,130 were men, equivalent to 49 percent of the total population, and 31,687,990 were women, equivalent to 51 percent.

In Mainland Tanzania, out of the 59,851,347 people counted, 29,137,638 were men, representing 49 percent of the total population in Mainland Tanzania, while 30,713,709 were women, representing 51 percent.

In Zanzibar, out of the 1,889,773 people counted, 915,492 were men, equivalent to 48 percent of the total population in Zanzibar, and 974,281 were women, equivalent to 52 percent.

This population increase signifies a large and continuously growing market, an expanding workforce, and rising demand for products and services, creating a favorable environment for sustainable investment in Tanzania.



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The primary Legal frame work governing pharmaceutical industry in Tanzania

The pharmaceutical industry is governed by the Tanzania Medicines and Medical Devices Act, Cap. 219 R.E. 2023, which establishes the legal framework for the regulation of medicines and medical devices. Within this legal framework, the Ministry of Health of the United Republic of Tanzania serves as the principal government authority responsible for health sector policy formulation and oversight, exercising powers and functions conferred by the president of the United Republic of Tanzania under Government Notice No. 57B of 24 January 2022 on the Assignment of Ministerial Functions. And other laws such as: The Pharmacy Act, Chapter 311 R.E. 2023, The Standards Act Cap 130 Revised 2023, The Industrial and Consumer Chemicals (Management and Control) Act (Cap. 182, R.E. 2023), The Public Health Act. [CAP. 99 R.E. 2023], Environmental Management (Amendment) Act, 2025 and so many others.

Tanzania's Health Sector Authority

The pharmaceutical sector in Tanzania is primarily supervised by the Ministry of Healthy. The Ministry of Health of the United Republic of Tanzania derives its mandate from the Assignment of Ministerial Functions issued by the President of the United Republic of Tanzania under Government Notice No. 57B of 24 January 2022. Through this Instrument, the President assigned the Ministry of Health the responsibility of formulating, coordinating, supervising, and implementing health-related policies and services in Tanzania.

Under this mandate, the Ministry of Health is responsible for providing policy direction, supervision, regulation, and coordination to government institutions, regulatory authorities, healthcare providers, investors, development partners, and stakeholders operating within the health and pharmaceutical sectors.

Under the same Instrument, the Ministry is mandated to formulate and implement health policies and to oversee preventive and curative health services, chemical management services, medical laboratory services, medical research and nutrition, food and drug quality services, medical supplies, promotion of traditional and alternative medicine, health services inspection, family planning, international health and medical organizations, coordination of non-governmental organizations and international organizations operating within the sector, performance improvement and human resource development within the Ministry, and supervision of extra-ministerial departments, parastatal

organizations, and projects under the Ministry.
The Ministry is further responsible for the provision and coordination of hospital services, preventive services, chemical management services, forensic science services, food and drug quality services, reproductive health services, promotion of traditional medicine, inspection of health services, participation in international health and medical organizations, development of human resources, oversight of parastatal organizations and development projects, and supervision of government agencies under its mandate.

Note

These functions are conferred upon the Ministry by the President of the United Republic of Tanzania through Government Notice No. 57B of 24 January 2022 on the Assignment of Ministerial Functions.

Executive Agency under the Ministry of Health in Tanzania (TMDA)

Tanzania Medicines and Devices Authority (TMDA) is an Executive Agency under the Ministry of Health (MOH). TMDA which was formerly known as Tanzania Food and Drugs Authority (TFDA) was established in 2003 after enactment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 by the Parliament.
This Act was later amended in 2019 to Tanzania Medicines and Medical Devices Act, Cap 219 after the shift of responsibilities of regulating food and cosmetics to Tanzania Bureau of Standards (TBS). The change in legislative framework which was done through the Finance Act, No. 8 of 2019 also resulted into the change of name to TMDA.
TMDA is now responsible for regulating quality, safety and effectiveness of medicines, medical devices, diagnostics, biocidal and tobacco products. In order to improve public service delivery, TMDA is managed as an Executive Agency in accordance with the Executive Agencies Act, Cap. 245 which was also amended.
Tanzania has established a clear and reliable legal framework governing the pharmaceutical and medical devices industry through the Tanzania Medicines and Medical Devices Act, Cap. 219 R.E. 2023. Under Sections 4, 5, and 6 of the Act, the law establishes the Tanzania Medicines and Medical Devices Authority (TMDA) as the official regulatory authority responsible for overseeing the safety, quality, registration, manufacture, importation, distribution, and sale of medicines and medical devices in the country.
The Act grants TMDA broad legal powers to regulate and supervise the pharmaceutical sector, including the authority to approve and register pharmaceutical products, license manufacturers and importers, inspect facilities, monitor clinical trials, and ensure compliance with international safety and quality standards. The Authority is also empowered to take enforcement measures against substandard or unsafe products, thereby protecting consumers and strengthening investor confidence in the Tanzanian market.

Roles and Functions of (TMDA)

Pursuant to the Tanzania Medicines and Medical Devices Act, Cap 219, TMDA regulates the manufacturing, importation, distribution, and sale of medicines, medical devices, diagnostics, biocidal products, and tobacco products. It is also responsible for setting standards of quality, safety, and effectiveness for these regulated products to ensure public health protection.
The Authority inspects manufacturing industries and business premises involved in regulated products to ensure compliance with required standards. It evaluates and registers medicines, medical devices, diagnostics, biocidal products, and tobacco products before they are authorized for marketing, and issues business permits for premises dealing with these products.
TMDA also assesses the quality, safety, and efficacy of controlled drugs and conducts laboratory analysis to verify product specifications. In addition, it carries out pharmacovigilance and vigilance activities for medicines, medical devices, diagnostics, biocidal products, and tobacco products circulating in the market.
Furthermore, the Authority promotes the rational use of medicines, medical devices, diagnostics, and biocidal products, while also educating and providing accurate, reliable information to stakeholders and the general public on regulatory matters. It ensures that tobacco products circulating in the market meet requirements that protect public health.
The existence of a legally empowered and internationally oriented regulatory authority demonstrates Tanzania's commitment to developing a competitive pharmaceutical industry capable of supporting local manufacturing, medical innovation, importation, distribution, and regional trade within East Africa and beyond.
For investors, this means Tanzania offers not only a growing market and expanding population, but also a stable regulatory system backed by law, designed to facilitate safe business operations and long-term investment growth in the pharmaceutical sector.

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Business Registration and Licensing Agency (BRELA)

The Business Registrations and Licensing Agency (BRELA) is an Executive Agency under the Ministry of Investment, Industry and Trade It was established under the Government Executive Agencies Act No. 30 of 1997 and formally launched on 3rd December 1999. The authority is responsible for business administration and regulation of the laws namely; the Companies Act, Cap.212 Business Names Act, Cap. 213. the Trade and Service Marks Act, Cap. 326 the Patent Registration Act, Cap. 217, the Business Licensing Act, Cap. 208 and the National Industries (Licensing and Registration) Act, Cap. 46.

Before engaging in pharmaceutical activities, a company must first be incorporated or registered with BRELA and obtain a certificate of incorporation or business name registration.

The Business Licensing Act, Cap. 208, R. E 2023 lays down the procedure, requirements and set the terms and conditions for the Application, issuance, validity and administration of the business licenses in Tanzania.

Under the Trade and Service Marks Act, the registration of trade and service marks is administered by BRELA through the Registrar of Trade and Service Marks. Section 21 of the Act provides that an application for registration shall be made in writing to the Registrar and must contain particulars including the name and address of the applicant, description of the business, reproduction of the mark, and the goods or services for which registration is sought.

BRELA as the Registrar of Patents in Tanzania

BRELA acts as the official government agency responsible for the registration and administration of patents, Industrial designs and Utility Models in Tanzania. BRELA receives and processes patent, and utility models applications submitted by inventors or companies seeking legal protection for their inventions.

Note; BRELA does not issue any pharmaceutical operating license, it is only issuing a legal business identity and administers intellectual property rights.

Tanzania Revenue Authority (TRA)

The Tanzania Revenue Authority (TRA) was established by Act of Parliament No. 11 of 1995, and started its operations on 1st July 1996. In carrying out its statutory functions, TRA is regulated by law, and is responsible for administering impartially various taxes of the Central Government.

The Tanzania Revenue Authority (TRA) regulates taxation of pharmaceutical businesses under the Tanzania Revenue Authority Act, Cap. 399 R.E 2023 and The Income Tax Act, Chapter 332 R.E 2023. Every pharmaceutical business must register for a Taxpayer Identification Number (TIN) and comply with tax obligations such as corporate tax, VAT, and import duties. TRA ensures that pharmaceutical trade and imports are properly taxed and that businesses operate within the national revenue framework. Without TRA registration, a business cannot legally conduct commercial pharmaceutical transactions.

Tanzania Investment and Special Economic Zones Authority (TISEZA)

The Tanzania Investment and Special Economic Zones Authority (TISEZA) is the newly established apex body under the Tanzania Investment and Special Economic Zones Act No. 6 of 2025 which is responsible for all matters related to investment promotion, coordination, facilitation, the development and management of Special Economic Zones and advising the Government on investment and Special Economic Zones matters to continually improve the investment climate.

Formed through the merger of the former Tanzania Investment Centre (TIC) and the Export Processing Zones Authority (EPZA), TISEZA aims to create a streamlined, efficient, and more investor-friendly environment. This consolidation repealed and replaced the Tanzania Investment Act, 2022, the Export Processing Zones Act, 2002, as well as the Special Economic Zones Act, 2006.

TISEZA is explicitly designed to be the first and primary point of contact for all investors interested in Tanzania. This is a crucial aspect of the Tanzanian government's ongoing reforms to streamline the investment process and create a more investor-friendly environment.

Roles And Functions of TISEZA

TISEZA acts as a single point of contact for investors, simplifying the process of obtaining permits, licenses, and approvals from various government agencies, including an integrated electronic system for online investment facilitation services. It functions as a comprehensive One Stop Facilitation Centre where investors can initiate and process most of their requirements through one institution, reducing bureaucratic hurdles, saving time, and providing a centralized point of accountability.

Investment Promotion: TISEZA promotes Tanzania as a prime investment destination to both domestic and foreign

investors, encouraging Foreign Direct Investment and making it easier for businesses to establish operations in the country, thereby strengthening Tanzania's position as a regional investment hub.
Special Economic Zones (SEZs) Development: It is responsible for identifying, designating, developing, and managing SEZs, including Export Processing Zones (EPZs), to attract strategic investments, boost exports, and support industrialization, while offering investment incentives.
Investor Facilitation and Aftercare, It provides ongoing support to investors, assists in navigating regulatory frameworks, and resolves investment-related complaints.
Land Bank Management: It establishes and manages a national land bank to catalogue public and registered private land available for investment, improving land access and streamlining acquisition, while reducing challenges in finding suitable and affordable land.
Investors Registration, Under the Investment and Special Economic Zones Act No. 6 of 2025, all investors are required to register before commencing operations in Tanzania, ensuring full oversight of investment activities.
Consolidated Mandate, it was formed through the merger of the former Tanzania Investment Centre (TIC) and the Export Processing Zones Authority (EPZA), creating a unified investment authority.
Comprehensive Information and Guidance, It provides information on investment opportunities, incentives, legal frameworks, and procedures from entry to implementation and aftercare.
Streamlined Services, it operates a unified electronic platform to centralize and digitize investment services, improving efficiency and transparency.
Access to Incentives and SEZs: It issues investment certificates and SEZ licenses and provides access to fiscal and non-fiscal incentives.
Dispute Resolution and Aftercare: It handles complaints and supports dispute resolution while ensuring continued investor assistance.
By centralizing these functions, TISEZA enhances ease of doing business in Tanzania, attracts investment, creates jobs, and supports economic growth and industrial development.
The Tanzania Investment and Special Economic Zones Authority (TISEZA) regulate large-scale pharmaceutical investments and industrial development under section 4 the Investment and Special Economic Zones Act [CAP. 38 R.E. 2023] TISEZA issues investment certificates and provides incentives such as tax exemptions and duty relief for approved investors. It also manages Special Economic Zones where pharmaceutical manufacturing may be established.
Note; This authority is particularly important for local and foreign investors and large pharmaceutical production facilities only.

Investment thresholds

This Is categories into three (3) as follows:

- **Normal investors**

foreign investors USD 500,000
Local investors USD 50,000

ii) Strategic investors:
foreign investors or a joint venture USD 50,000,000
local investors USD 20,000,000
Note to be regarded as a strategic investor the following qualification must be met:

- At least one thousand local employment is created with satisfactory number of senior positions in projects that do not require high and sophisticated technology.
- Capability of export at least fifty percent of goods produced or produce import substitution goods.
- Capability of stimulating production by establishing industrial parks in various social and economic sectors
- Enhances technical know- how by imparting new technology to the Tanzanians;
- Spe capability to produce goods or render services necessary for development in the social and economic sectors considering priorities for the time being.

- **Special strategic investors: USD300,000,000**

Conditions under this category is that, investment business transaction must be undertaken through a registered local financial and insurance institution;
At least one thousand five hundred direct local employment is created with Certis factory number of senior position in the project that do not require high and sophisticated technology and capability to significantly generate foreign exchange earnings, produce significant import substitution goods or supply of important facilities necessary for development in the social, economic or financial sector.

Local Government Authorities (Trade Licensing)

Local government authorities, including municipal councils, regulate day-to-day business operations. Section 159 of the Local Government (District Authorities) Act [Cap. 287 R.E. 2023] provides the legal basis for a district authority to issue and regulate business license through its by-laws. Under section 159(1), by-laws may prescribe reasonable fees and charges in relation to any license, permit or other instrument issued under such by-laws, and may impose conditions for their issuance and compliance.

Furthermore, section 159(2) empowers the authority and its officers to exercise powers of inspection and enforcement necessary for the implementation of the by-laws, while section 159(3) authorizes the cancellation of a license or permit where the licensee contravenes the conditions attached to it. Therefore, this provision supports the authority of the local government authority to issue, supervise and enforce pharmaceutical business license within its jurisdiction. And the Local Government (Urban Authorities) Act [Cap. 288 R.E. 2023].

These authorities issue business operating licenses (trade licenses) and ensure compliance with local zoning, health, and safety requirements. Even after obtaining national approvals from TMDA, BRELA, and TRA, a pharmaceutical business must still secure a municipal license to legally operate within a specific locality.

The authority of urban and district councils to regulate and issue trade license under the Local Government (Urban Authorities) Act [Cap. 288 R.E. 2023] and the Local Government (District Authorities) Act [Cap. 287 R.E. 2023] is mainly derived from their statutory powers to regulate economic activities within their areas.

Where Licenses Are Found

Pharmaceutical regulation in Tanzania operates through a coordinated system of multiple authorities. The company registration certificate is issued by BRELA, while the core pharmaceutical licenses (premises and product registration) are issued by TMDA. The tax registration (TIN and compliance certificates) is issued by TRA, and investment approvals are granted by TISEZA under the Investment Act. Finally, the trade operating license is issued by local government authorities (municipal councils). Each institution plays a distinct legal role, and all licenses are required collectively for a pharmaceutical business to operate lawfully in Tanzania.

Legal Services on Pharmaceutical industry in Tanzania by Dar State Attorneys

- The firm assists clients with company incorporation and business registration through Business Registrations and Licensing Agency (BRELA). Such as registration of companies, business names, foreign entities, patents, utility models, trade and service marks, as well as, obtaining municipal trade licenses and operational approvals this including preparation of all necessary documents of the registration.
- The firm also assists clients in obtaining pharmaceutical licenses and regulatory approvals from Tanzania Medicines and Medical Devices Authority (TMDA), including premises licenses, product registration, import and export permits, and compliance with pharmaceutical regulations.
- The firm provides legal advisory services relating to inspections, regulatory compliance, and administrative proceedings before regulatory authorities. including support, compliance representation.
- DarState Attorneys advises clients on tax and investment matters before the Tanzania Revenue Authority (TRA) and Tanzania Investment and Special Economic Zones Authority (TISEZA), including TIN registration, investment incentives, commercial agreements, corporate compliance, and general business advisory services.
- The firm provides intellectual property and consultancy services, including trademark registration, copyright protection, patent registration, intellectual property advisory. industrial design registration and IP enforcement.
- The firm assists clients in obtaining pharmaceutical licenses and regulatory approvals from Tanzania Medicines and Medical Devices Authority (TMDA), including premises licenses, product registration, import and export permits, and compliance with pharmaceutical regulations.

Conclusion

The coordinated roles of TMDA, BRELA, TRA, TISEZA, and Local Government Authorities ensure that investors operate within a transparent, predictable, and legally secure environment that promotes quality, safety, and compliance. In this regard, we offer comprehensive pharmaceutical investment facilitation services, including regulatory guidance, licensing support, company establishment assistance, tax compliance advisory, and investment structuring to ensure smooth and successful operation within the Tanzanian market. Our role is to facilitate and enable investors to efficiently establish and grow sustainable pharmaceutical businesses in Tanzania.

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