

# HEALTHCARE DELIVERY INVESTMENT IN TANZANIA

“TMDA LEGAL FRAMEWORK AND PHARMA INVESTING  
IN TANZANIA”

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CHINA EXPO2023,  
June 2023

Presented by TMDA

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# Outline

- Legal Framework
- TMDA Services
- Pharma and Medical Devices  
Manufacturing – at a glance
- Establishing a Manufacturing facility in  
Tanzania
- Procedures and timelines for registration
- Investment Opportunities and Incentives
- Conclusion

# The Legal Framework

- **National Health Policy, 2007** (currently under review) “ .....encourage growth of local public and private medical products manufacturing facilities in order to enhance self-reliance in the production of essential medical products”
- **The Tanzania Medicines and Medical Devices Act, Cap 219** “ among other functions... it regulates the manufacturing, importation, exportation, storage, distribution and sale of medicines, medical devices and diagnostics. Hence, a number of regulations, guidelines and simplified procedures have been developed to facilitate conducive business environment
- **Tanzania Development Vision 2025** (Tanzania’s third Five-Year Development Plan) – of which one of its strategic objectives is *to build a strong and resilient economy that can effectively withstand global competition - diversified economy with a substantial industrial sector*

- **National Industrialization Agenda 2025**

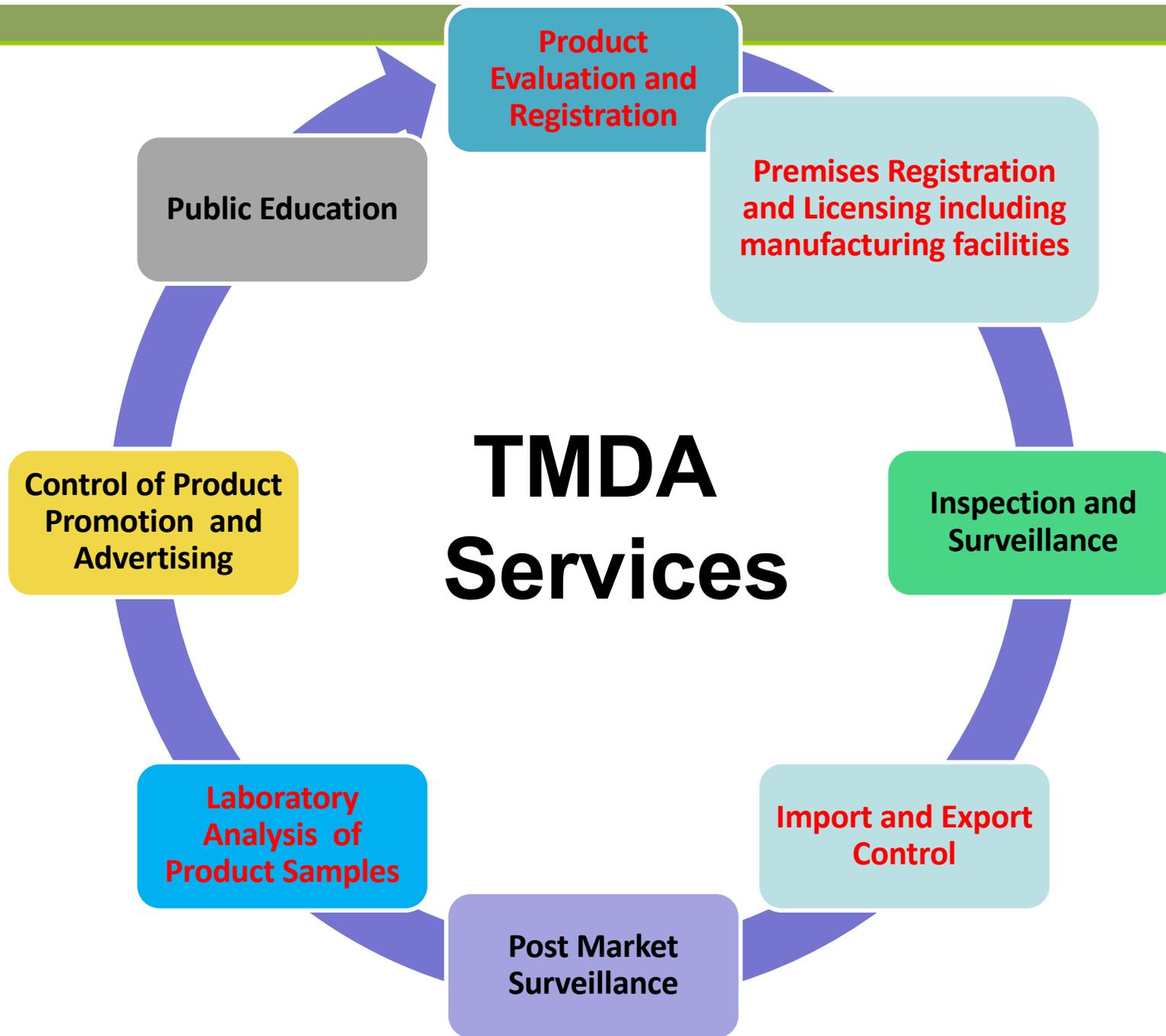
“ aims at Tanzania becoming a semi-industrialized country by 2025, for which the contribution of the manufacturing to the national economy must reach a minimum of 40% of the Gross Domestic Products (GDP)”

- **Health Sector Strategic Plan 5 (HSSPV): July 2021- June, 2026**

“ has prioritized the strengthening of domestic manufacturing facilities including research and development....”

- **TMDA Strategic Plan 2021/22 – 2025/26**

- **TMDA Action Plan** to promote domestic medical products manufacturing facilities 2022/23 -2026/27 (recently developed and awaiting stakeholders discussion)



# Pharma & Devices Manufacturing in Tanzania – at glance

## Human Medicines (11 facilities)

- **Seven (7) Oral Formulations**
- **One (1) large scale for SVP (infusions)**
- **3 External Formulations**
- **11 under construction (among them 3 large scale)**

## Veterinary Medicines (6 facilities)

- **Five (5) small to scale formulations (oral & vaccines)**
- **One (1) large scale for biologicals (vaccines)**

## Medical Devices (24 facilities)

- **24 small scale manufacturing facilities for devices such as medical gauzes, face masks, baby diapers etc.**
- **No manufacturing facilities for Diagnostics**

## ..... Pharma & Devices (contd)



- 🌿 By 2021:
- 🌿 >80% Medicines were being Imported
- 🌿 ≈Approx. 4,000 Brands of registered medicines
- 🌿 Imported medicines FOB ≈USD 186,578,391
- 🌿 In 2021= Domestic production value was about 20%

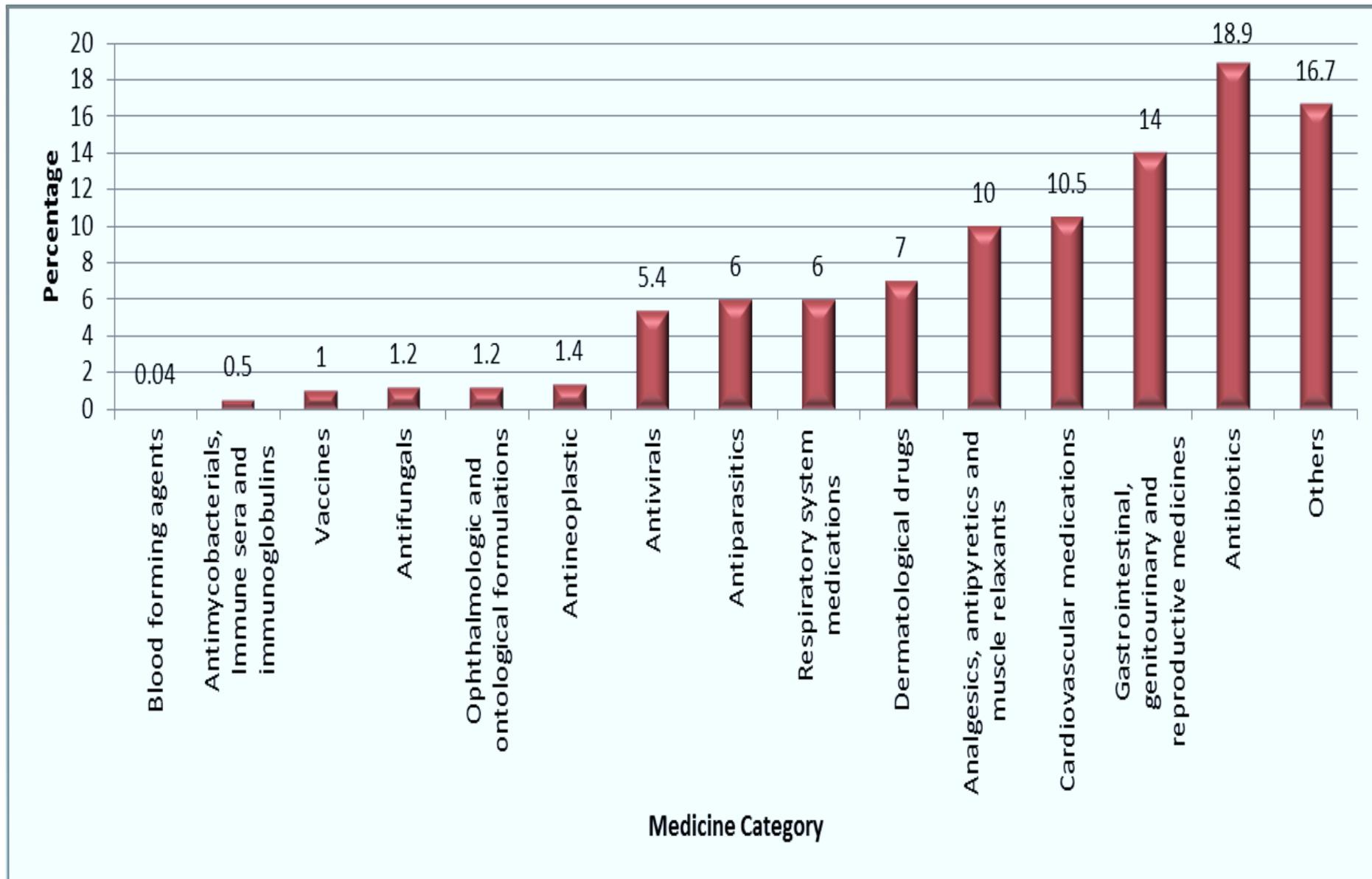


## **MEDICAL DEVICES (MD) AND DIAGNOSTICS**

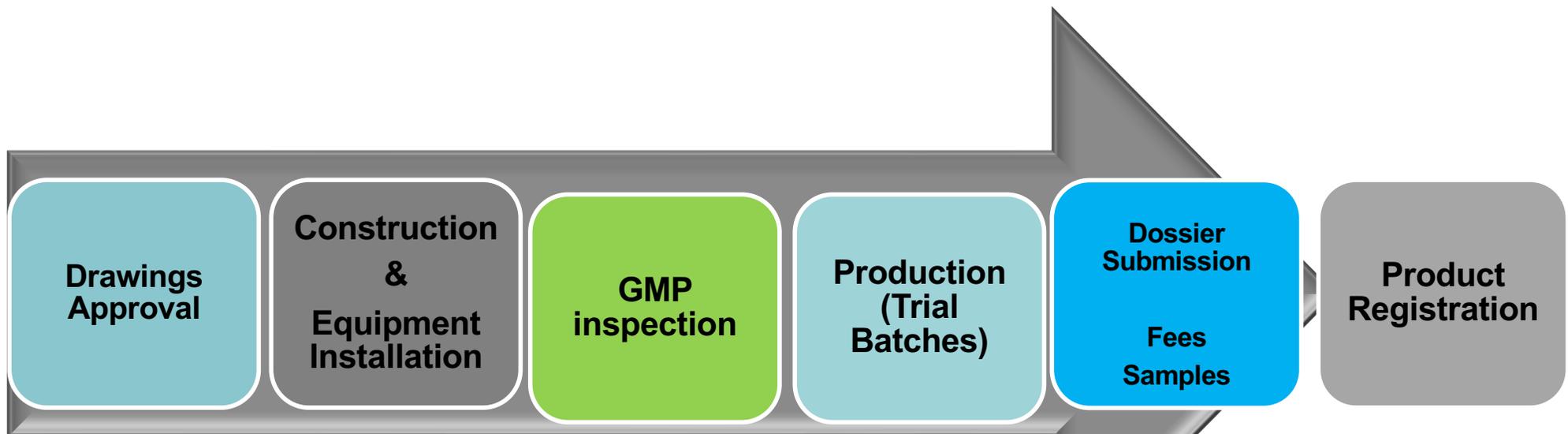
### **By 2021:**

- **>90% MD and 100% Diagnostics were being imported**
- **Approx 1,417 MD and 611 in-vitro diagnostics have been registered**
- **Imported MD & Diagnostics accounted approx. 139,000,000 USD (FoB)**

# Registered Medicines Category (2021) -Trends

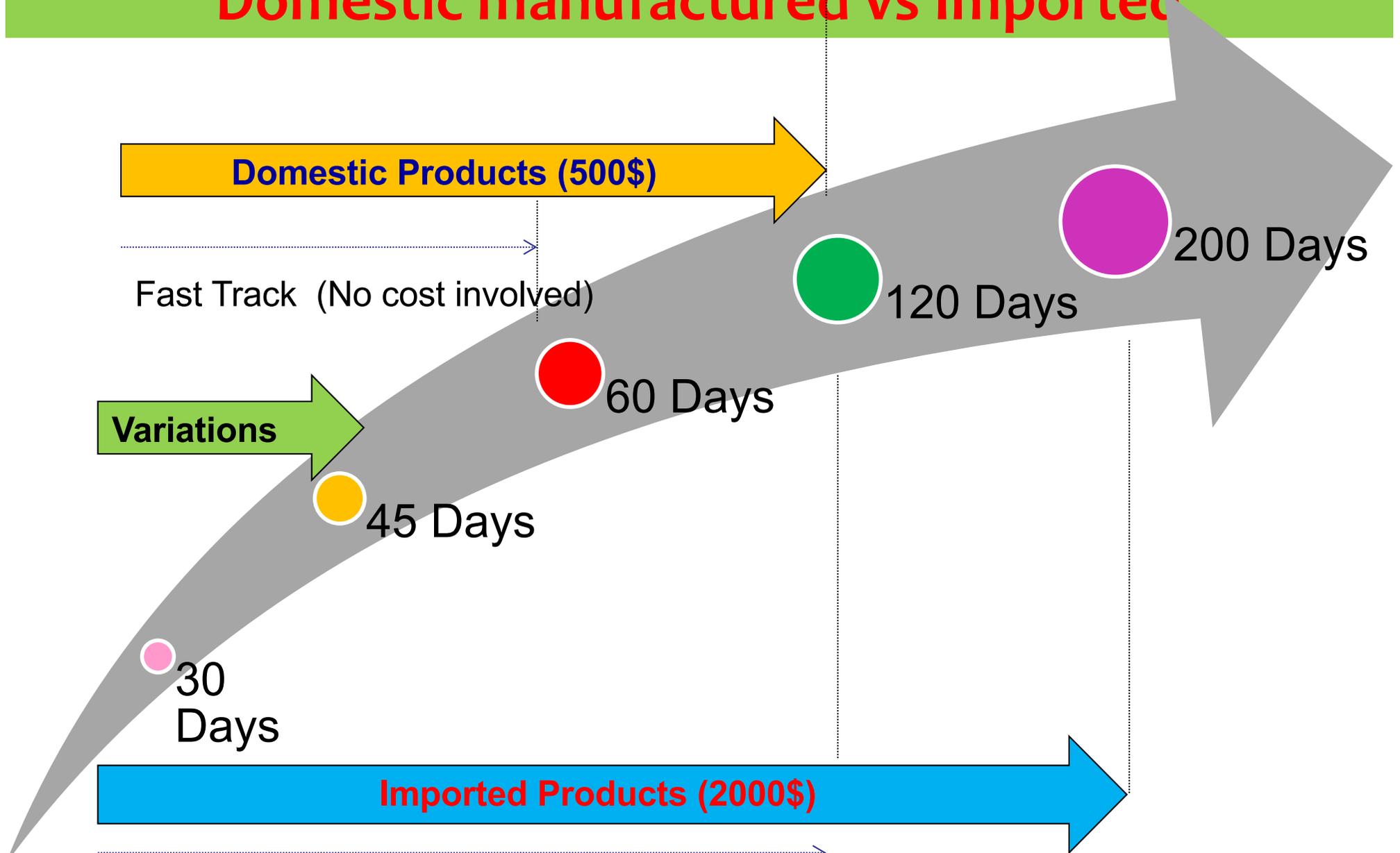


# Establishing a manufacturing facility in Tanzania – the pathway



# Registration Fees and Timelines

## Domestic manufactured vs Imported



**Domestic Products (500\$)**

Fast Track (No cost involved)

**Variations**

30 Days

45 Days

60 Days

120 Days

200 Days

**Imported Products (2000\$)**

Fast Track (at a cost)

# TMDA Support to Domestic manufacturers



Time reduced (From 6 to 3 months)



No GMP Fees



No Importation fees

(Materials- Raw, Packaging and Machines)



Reduced registration fees



Facility Staff Trainings



Regular Meetings



Technical Support

- Why Invest in Tanzania?



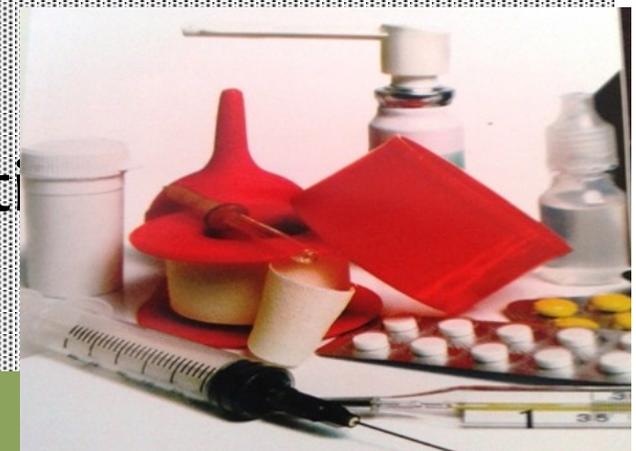
# Investing in Tanzania...opportunities



- Strategic geographical location (bordering 8 countries of which 6 are LLC, 3 major ports and 3 International Airports)
- Access to Tanzania (approx. 60 million), EAC (162 million) and SADC (450 million) market
- Peace and Sound political stability (multiparty, democracy, good governance, stable post – election and no civil wars)
- Bulk procurement by Government through MSD for SADC
- Reputable & strong Regulatory Authority in Africa (WHO - ML3)
- Few narrow range of generic products registered
- Limited number of sterile products manufacturing plants

# Opportunities

- ❖ No manufacturer of ARVs, anti-Tb, anticancer, cardiovascular Medicines
- ❖ No API or excipients bulk dealers /manufacturing facility, only **small scale manufacturers** of packaging materials available (erratic supply)
- ❖ No **supplier of manufacturing and laboratory** equipment / supplies
- ❖ **National Health Insurance scheme for Universal coverage**
- ❖ WHO prequalified Regulatory Lab.
- ❖ Existence of Orphan Medicines Regulation



## Opportunities.....

-  **>80% of medicines, >90 % of medical devices and 100% diagnostics are imported**
-  Utilization of TRIPS flexibilities for manufacturing of new molecules which are still under patent
-  Muhimbili University Pharm R&D lab support in conducting and generating BE data
-  **Possibility for establishing specialized training centres, provision of spare parts, chemicals, reagents and various technical support (equipment maintenance)**

# Other incentives for Medical products investments

## Tax Incentives

- Project Capital Goods
  - Import duty – 0%
  - VAT -0%
- Deemed Capital Goods
  - Import duty – Exempted by 75%
- Capital Allowance
  - Manufacturing – 50%

# Non – Tax Incentives

- Automatic immigration quota of up to 5 expatriates at the initial stage of project
  - Assistance to obtain various permits, approvals and licenses such as:-
    - Company Incorporation
    - Business Licences
    - Industrial Licences
    - Tax Identification Number (TIN)
    - Work Permits
    - Residence Permit Class A& B
    - Environmental Impact Assessment (EIA)
    - Land Derivative Rights

# Conclusion

“We would like to encourage our esteemed (potential) investors to utilize the existing investment environment, opportunities and incentives to establish investments on medical products in Tanzania”

# Thank you (Asante, shukrani)



Serengeti National  
Park

Mt.Kilimanjaro

# Thank you

