MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

ACCESS TO MEDICINES AND HEALTH TECHNOLOGIES – REGULATORY FRAMEWORK AND INVESTMENT OPPORTUNITIES AVAILABLE IN TANZANIA

Official Visit of the Minister of Health of Tanzania to India
TAJ KRISHNA HOTEL
HYDERABAD – INDIA

29th July 2023

Adam Mitangu Fimbo
DIRECTOR GENERAL - TMDA

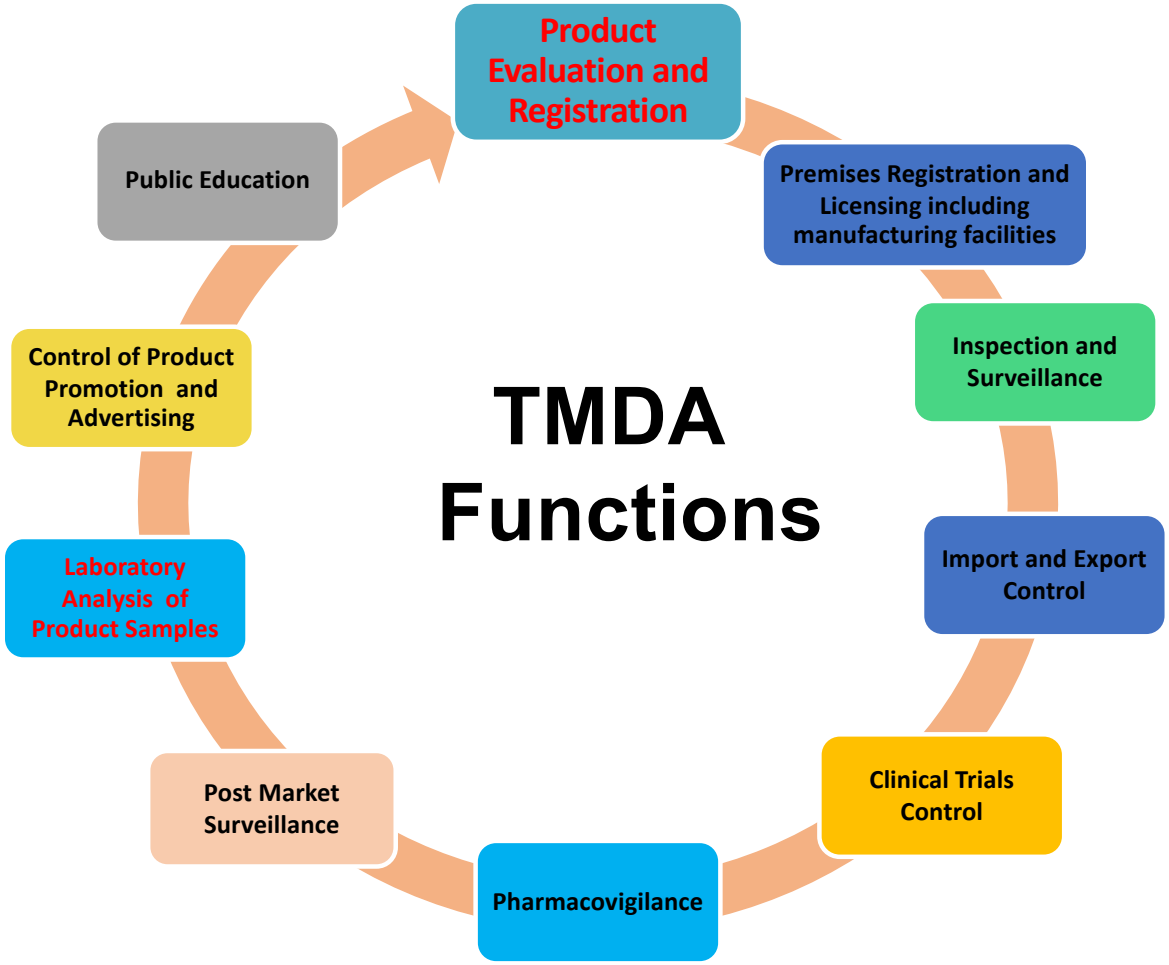
About TMDA

- **National Regulatory Authority** under the **Ministry of Health**
- Responsible for protecting and promoting public health
- Operating like the **Central Drugs Standard Control Organization (CDSCO) of India**
- Mandated by law (***The Tanzania Medicines and Medical Devices Act, Cap 219***) to regulate the **quality, safety** and **efficacy** of medicines, medical devices and diagnostics

Products Regulated

- **Medicines** – human, veterinary, biologics including vaccines, herbal (*but not traditional medicines*), antiseptics and disinfectants
- **Medical Devices and Diagnostics** – Class A, B, C and D
- Of recent - **Tobacco Products** (*after an Order issued by the Minister of Health under the* ***Tobacco Products (Regulation) Act, Cap 121*** - ***GN 360, published on 30/4/2021***)
  - Tobacco products are required to meet standards **appropriate for the protection of public health** as they are not safe for human use
- **Food products and cosmetics** are regulated by the Tanzania Bureau of Standards (TBS) – under the Ministry of Industry and Trade

Regulatory Systems/Functions (WHO - ML-3)

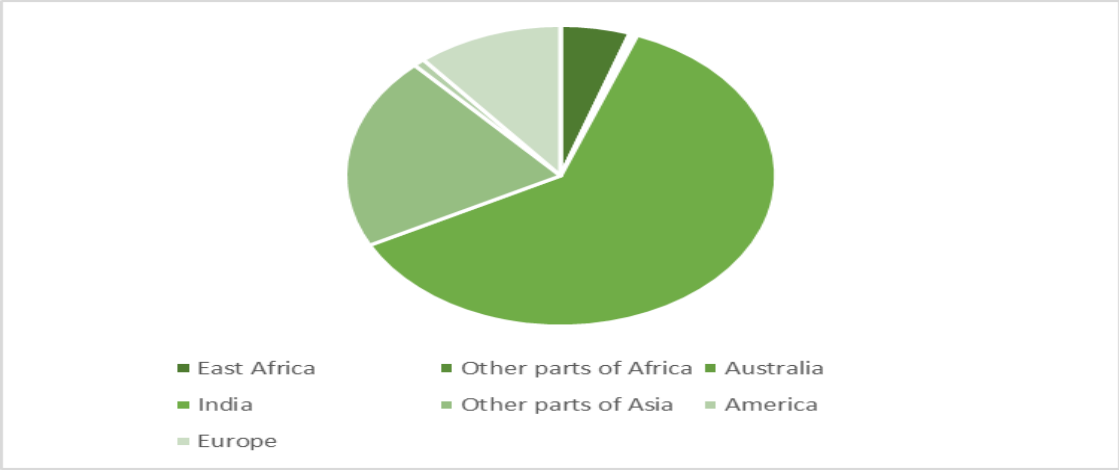


Marketing Authorization of Medicines

- TMDA receives around **900 - 1200** new applications for marketing authorization every year

- More than three-quarter of the applications submitted for registration are from **Asia (79.2% cumulatively),** with **59% (885 applications)** from **India** only

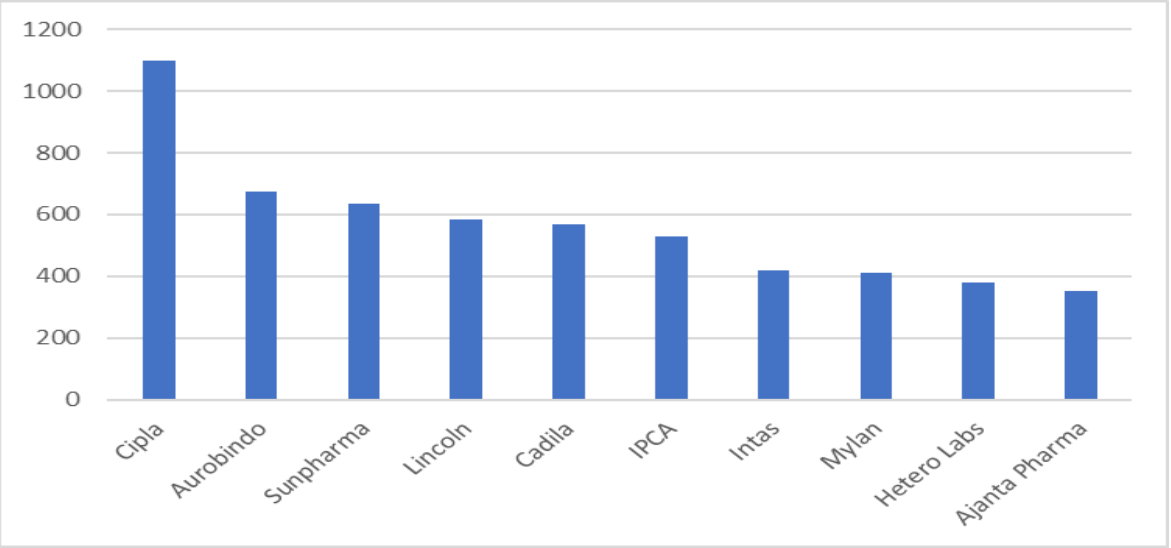
- **Other regions:**
  - Europe - 10.6%
  - Africa - 9.2%
  - America - 0.83%



Indian Medicines Manufacturing Facilities

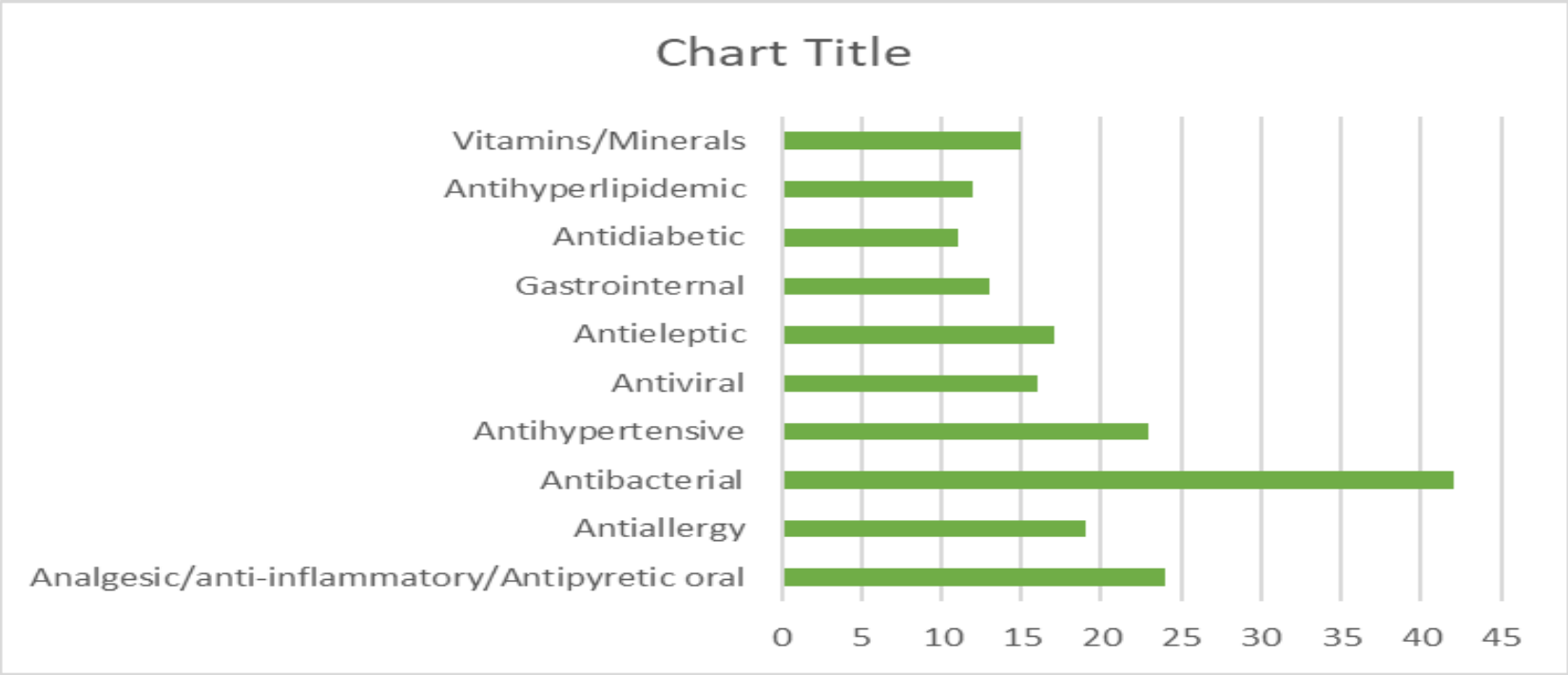
- As of to-date we have registered medicinal products from **447** manufacturing facilities from India
- **Top 10 facilities** with high number of submissions and registered products:

1. **Cipla Ltd**
2. **Aurobindo Pharma Ltd**
3. **Sun Pharmaceuticals Ltd**
4. **Lincoln Pharmaceuticals Ltd**
5. **Cadila Pharmaceuticals Ltd**
6. **IPCA Laboratories Ltd**
7. **Intas Pharmaceuticals Ltd**
8. **Mylan Laboratories Ltd**
9. **Hetero Laboratories Ltd**
10. **Ajanta Laboratories Ltd**



Therapeutic Classes

- Applications received from Indian manufacturing facilities cover all therapeutic classes of medicinal products
- However, top ten categories are these:



MA of Medical Devices and Diagnostics

From the global context:

- Medical devices and diagnostics registered so far - **1,967**
- Notified products (**Class A not requiring registration**) - **5,877**
- **Total – 7,844**

From India only:

- ✓Registered medical devices and diagnostics – **510**
- ✓Notified products – **1,404**
- ✓**Total – 1,914**

Device and Diagnostic Manufacturers

- As of to-date **104** manufacturers (**of Indian origin**) have submitted applications for registration of medical devices and diagnostics
- **151** manufacturers have submitted applications for notification (**Class A**)

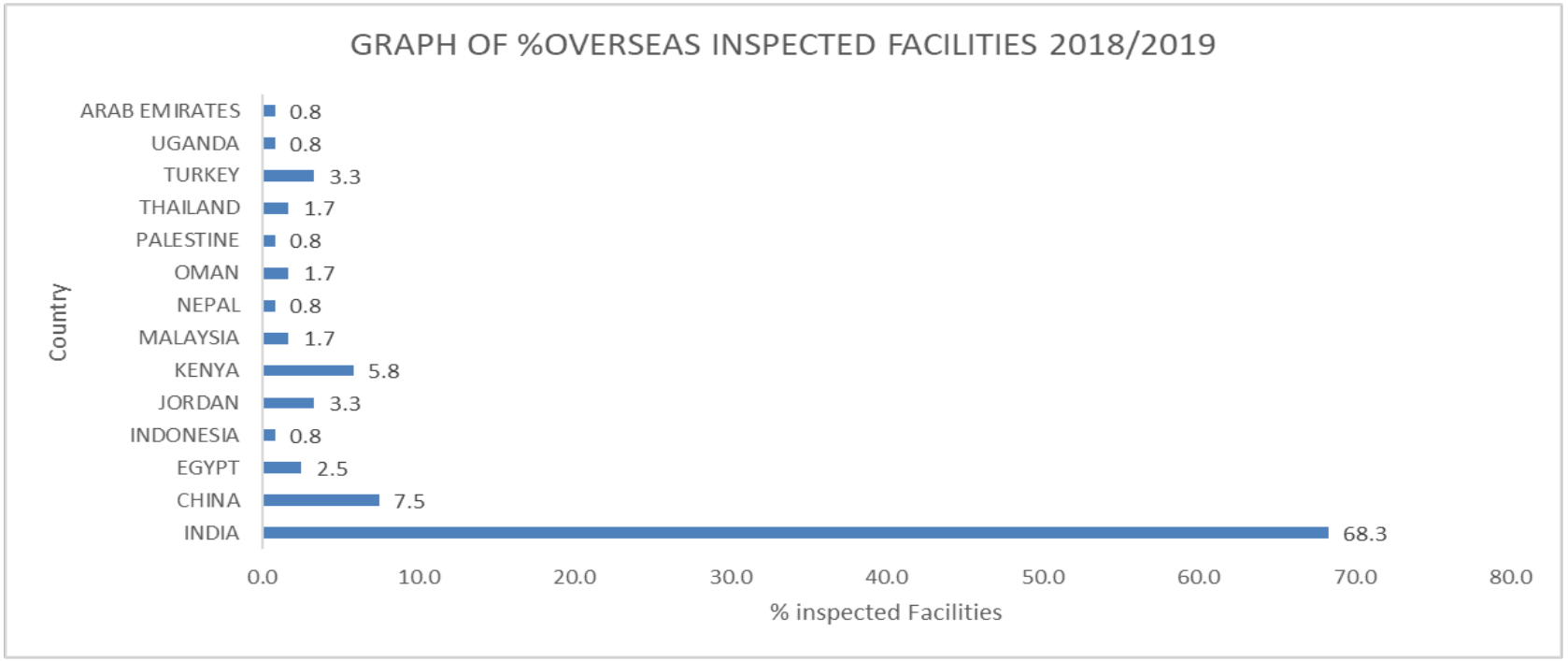
- **Top 10** products registered:- **absorbable and non-absorbable sutures, auto-disable syringes, IV cannulas, male latex condoms, surgical gloves, analyzers, infusion sets, implants, catheters and blood transfusion sets**

Top 10 MD manufacturing facilities of Indian origin

1. Polymedicure Limited
2. Lotus surgical Limited
3. Healthium Medtech PVT Limited
4. Agape Diagnostics Limited
5. Beacon Diagnostics PVT Limited
6. Microxpress
7. Ascent Meditech
8. Mediqip Healthcare Solution LLP
9. Tynor Orthotics PVT Limited
10. Aadhar Medicare PVT Limited

GMP Inspection (2018/19)

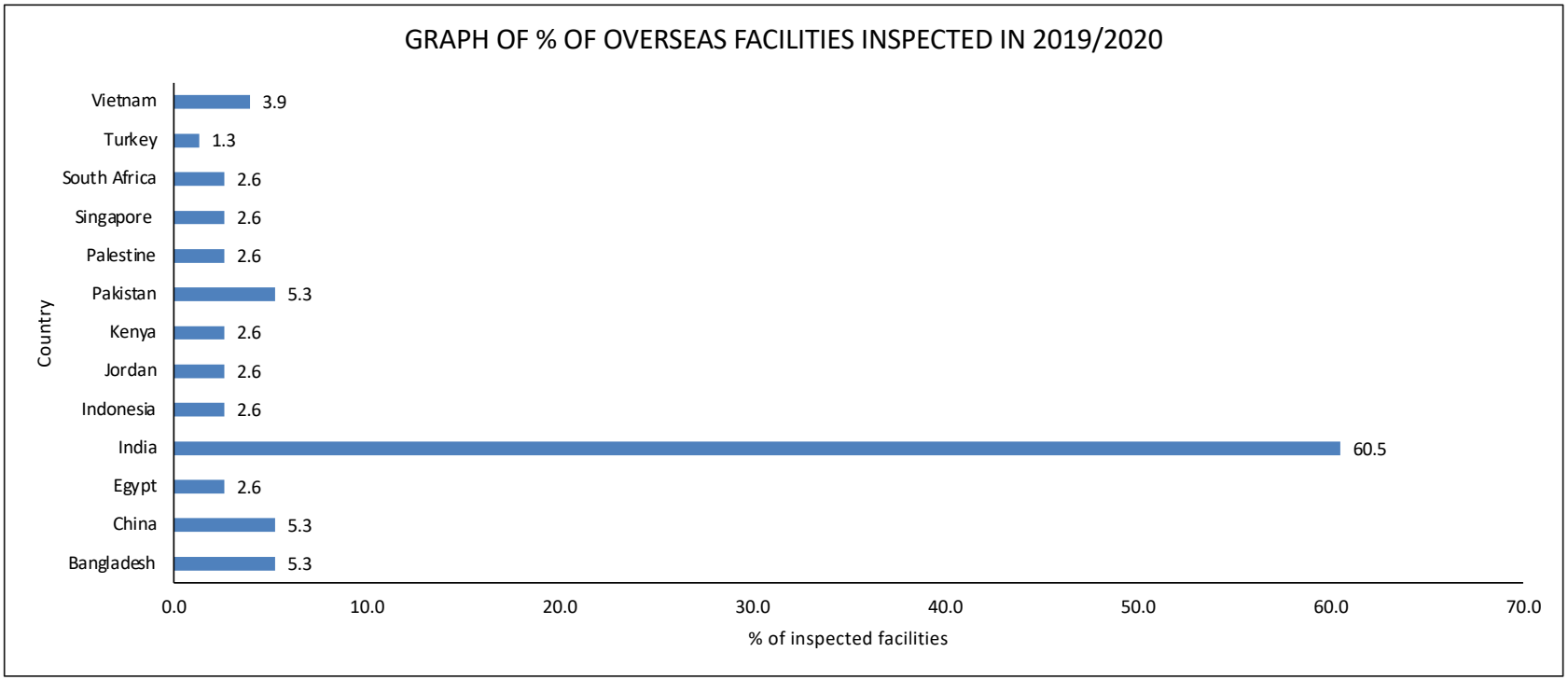
- TMDA inspected **120** overseas facilities in **2018/2019**



- **68.1% (n = 82)** facilities were in India

GMP Inspection (2019/20)

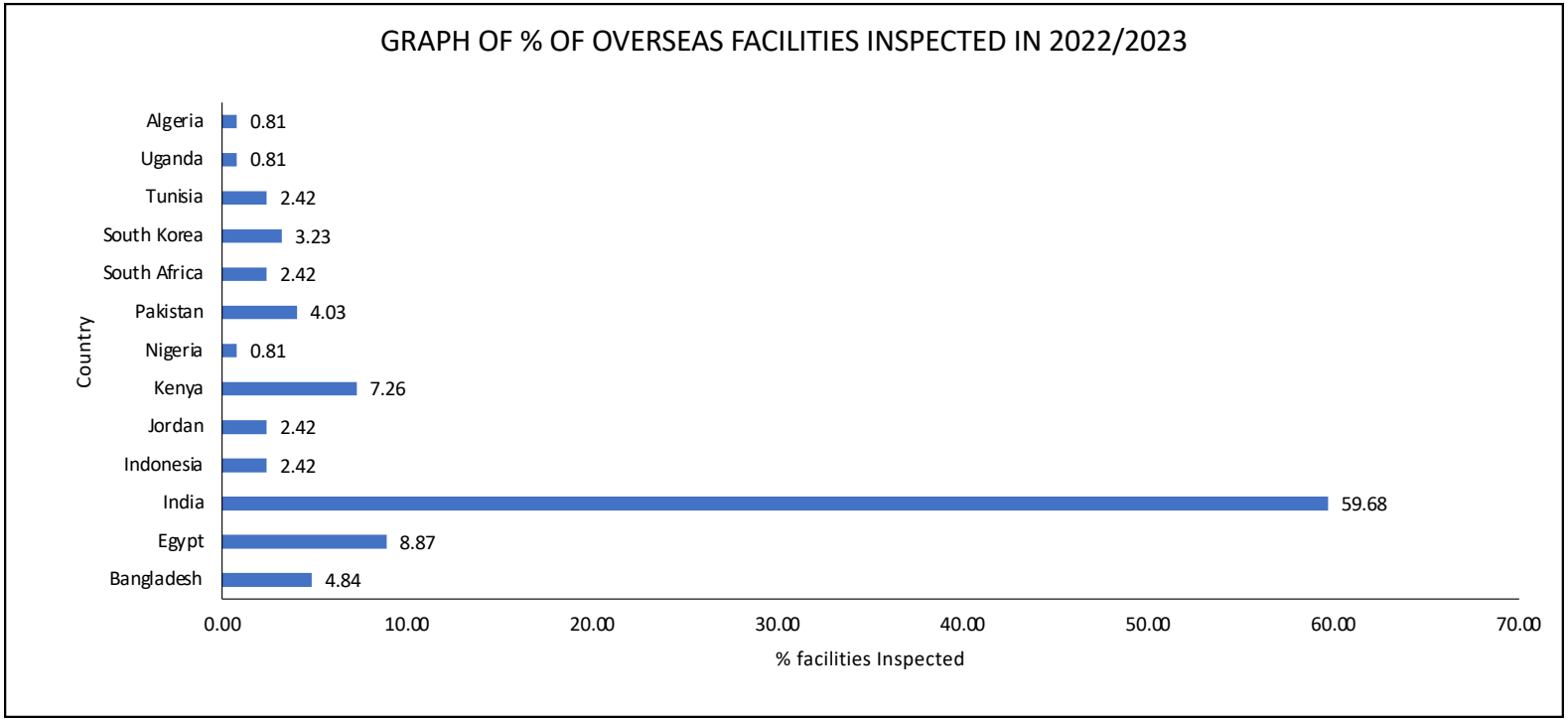
- TMDA inspected **76** overseas facilities in **2019/2020**



- **60.5% (n = 46)** facilities were in India

GMP Inspection (2022/23)

- TMDA inspected **124** overseas facilities in **2022/2023**

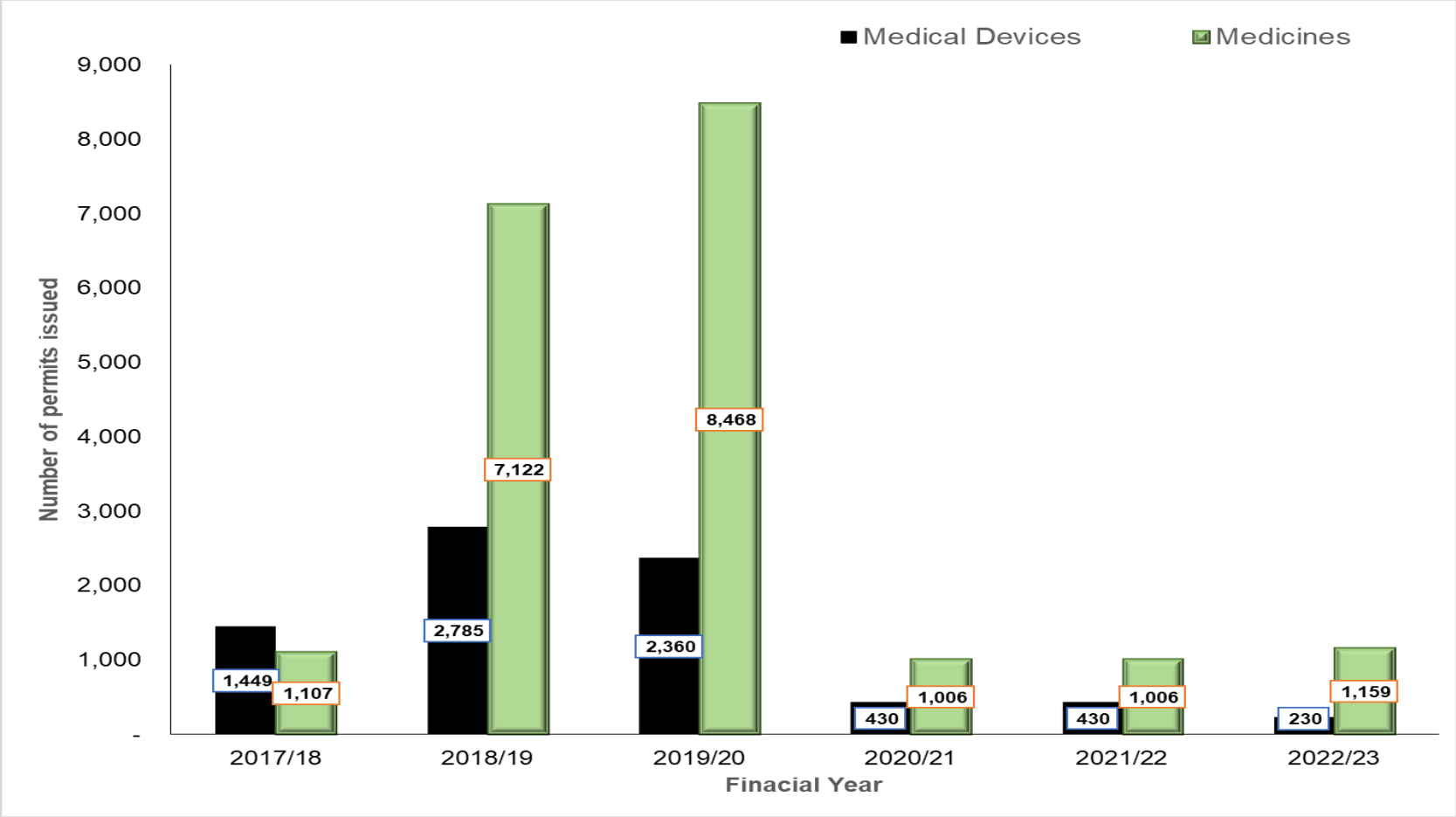


- **59.68% (n = 74)** facilities were based in India

Quality Audit of MD facilities

- Since 2017 – a total of **89** medical devices and diagnostics manufacturing facilities have been audited
- **33** manufacturing facilities in India only
- Between 2020 to 2022 - no physical inspection was done due to Covid-19 pandemic.
  - ***Adopted desk review and virtual inspection procedures***
- More than **70%** of facilities have complied with TMDA Regulations (**GN 315**), Guidelines and ISO Standards including **ISO 13485:2016**

Import permits issued for products from India



Gaps & Investment Opportunities

Despite the engagement of Indian manufacturers, importers and the entire business community in Tanzania, still there are gaps that can potentially be explored and taken advantage of:

- **>80%, 90% and 100%** of medicines, medical devices and diagnostics respectively are being imported
- Narrow range of generic products registered considering the therapeutic categories available
- Neither API nor excipients manufacturing facilities
- Few packaging materials manufacturing facilities (supply is erratic)

Gaps & Investment Opportunities….

- No biologics including vaccines manufacturing plants
- Limited number of sterile products manufacturing facilities (***only two established recently***)
- No manufacturers of medicines of public health and economic importance (**Anti-TBs, Anti-cancers, ARVs & 1st line Anti-malarials**)
- No suppliers of manufacturing and laboratory equipment, instruments, consumables, reagents and other supplies

Gaps & Investment Opportunities….

- Huge demand for medical devices (highly used in health facilities):
  - **Blood bags, gloves, cotton wools, syringes, needles, sutures, cannulas, dialysis consumables, x-ray films, orthopaedic implants, infusion sets, etc.**
  - **IVDs for malaria, HIV, Covid-19, UPT etc.**
  - **Spare parts**
  - **Accessories**

Competitive advantage

- Strategic geographical location (bordering 8 countries of which 6 are LIC, 3 major ports and 3 International Airports)
- Access to Tanzania **(63.59 million), EAC (295.1 million) and SADC (over 450 million)** market
- Peace and sound political stability (multiparty democracy, good governance, stable post – election and no civil wars)
- Bulk procurement by the Government through MSD
- Reputable & strong TMDA (WHO - ML3) incl. WHO Prequalified Laboratory
- Existence of the National Health Insurance Scheme
- Utilization of TRIPS flexibilities for manufacturing of new molecules which are still under patent

Pharmaceutical Market: EAC and SADC

Population Size: 295.1 million
EAC Pharmaceutical Market
US 5$ billion per annum

Population Size: 450 million
SADC Pharmaceutical Market
US 3$ billion per annum

Competitive advantage….

In 2022

- Imported medicines accounted for **FOB value** of **USD 186,578,391**
- Imported MD & Diagnostics accounted for approx. **139,000,000 USD** of **FOB value**
- Domestic production value was at **20%**

Other incentives for medical products investment

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 through Tanzania Investment Center (TIC) such as:-
  - **Company Incorporation**
  - **Business Licenses**
  - **Industrial Licenses**
  - **Tax Identification Number (TIN)**
  - **Work Permits**
  - **Residence Permit Class A & B**
  - **Environmental Impact Assessment (EIA)**
  - **Land Derivative Rights**

Harmonization of Regulatory Requirements in EAC & SADC

EAC Treaty
Chapter 21, Article 118

Harmonization of regulatory requirements, guidelines, standards and tools for medical products

- **ABREMA, Burundi**
- **PPB, Kenya**
- **Rwanda FDA, Rwanda**
- **DFCA, South Sudan**
- **NDA, Uganda**
- **DPM, DRC**
- **TMDA & ZFDA, Tanzania**

- **EAC Common Technical Document (CTD)**
- **EAC GMP Standards and Guidelines**
- **Technical Cooperation Framework Agreement for EAC & NMRAs**
- **Harmonized Guidelines for Vaccines, Biotherapeutics, Biosimilars, IVD's, Pharmacovigilance, Post-Marketing Surveillance , Clinical Trials & APIMF Procedure**

24 Joint GMP Inspections in Asia, 16 India

All sites compliant to EAC GMP Standards

233 Applications for Joint Scientific Review (all regions)

41 Applications Jointly Assessed – from India
23 Medical Products Approved for MA
18 Applications under different levels of review process

Median Time for Joint Scientific Review

- **Submission to end of assessment for all products: 53 to 221 working days**
- **Regulator's time: 44 - 391 working days**
- **Manufacturers' time to answer queries: 5 - 927 working days**

Access to Quality, Safe and Efficacious Medicines by Patients

Fees and Charges for Product Registration

Type of Fees	Tanzania (TMDA)	Uganda (NDA)	Kenya (PPB)
Medicines Registration	US$ 2,000 (Imported)	US$ 2000 (Imported)	US$ 1000 (Imported)
	US$ 500 (Domestic)	US$ 200 (Domestic)	US$ 200 (Domestic)
GMP Inspection	US$ 4,000 (East Africa) US$ 5,000 (Rest of Africa) US$ 6,000 (Asia) US$ 7,000 (Europe) US$ 8,000 (America)	US$ 5,000 (East Africa) US$ 6,000 (Rest of Africa) US$ 8,000 (Outside Africa)	US$ 4,000 (Foreign) US$ 1000 (Domestic)
	Domestic – Not chargeable	US$ 3,000 (Domestic)	US$ 1,500 (Domestic)
Retention	US$ 300 (Imported) Domestic Not charged	US$ 500 (Imported) US$ 100 (Domestic)	US$ 300 (Imported) US$ 150 (Domestic)

TMDA's Facilitative Approach

- Established a dedicated desk at Tanzania Investment Centre
- Part of **Single Window System** – government initiative to streamline/mainstream approval processes incl. permits
- Abolished GMP inspection and retention fees for domestic manufacturers and products respectively
- No importation fees for raw & packaging materials and machines
- Reduced registration fees from **USD 2500 to 2000** for foreign medicinal products and **USD 2000 to 500** for domestic products
- Reduced registration timelines from **365 to 180** working days for foreign products and **180 to 90** days for domestic products

TMDA's Facilitative Approach….

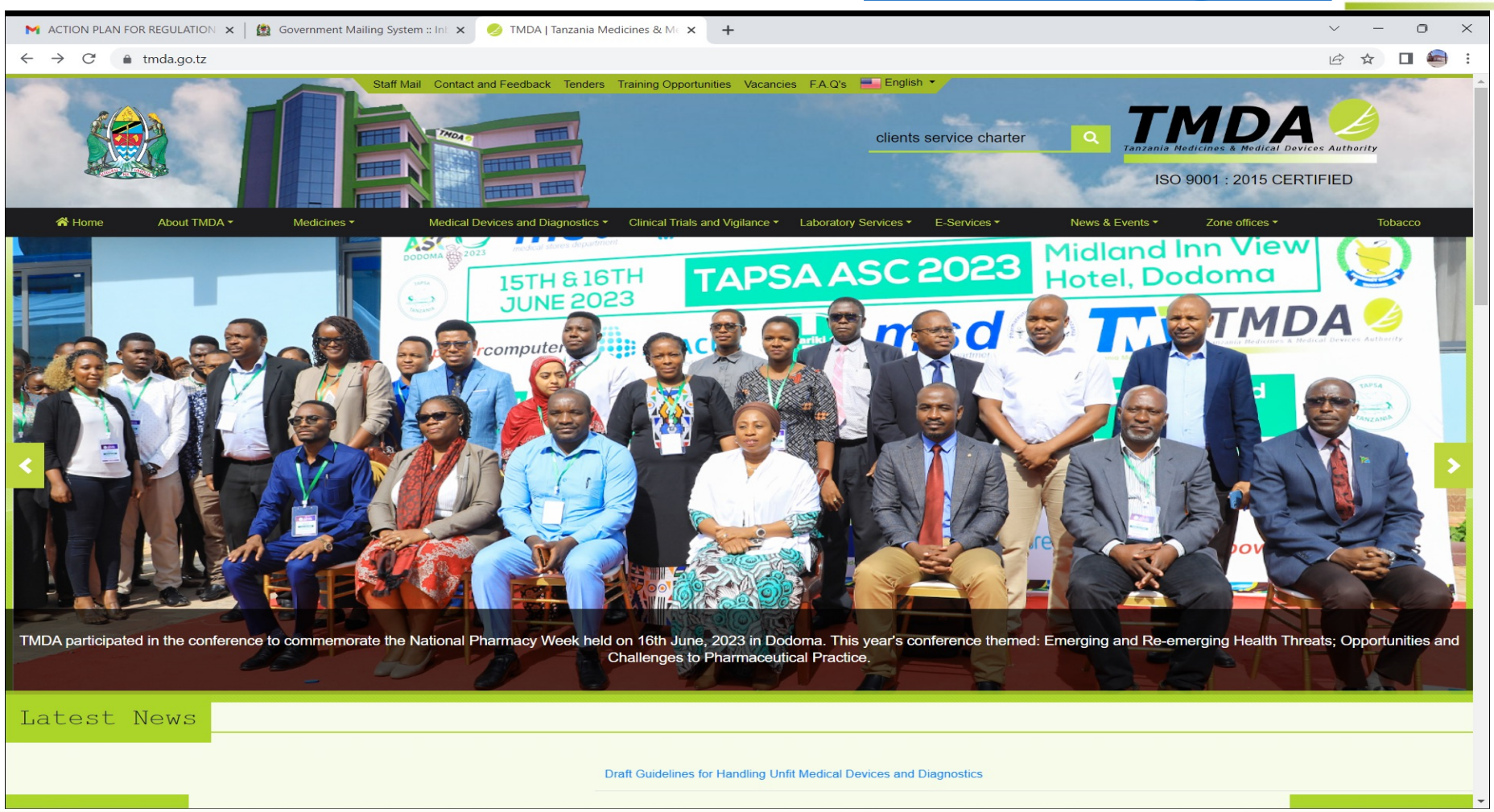
- Introduced fast-track mechanism to expedite approval process
- Approved ***Orphan Medicines Regulations***
- Expediting approval of industrial drawings/layouts for manufacturing incl. supervising construction operations at all stages
- Offering regular training and technical support on GMP and registration requirements to industry personnel
- Introduced abridged assessment procedure for WHO prequalified products, approved by SRAs & good PMS status
- Automatic approval of products assessed under **EAC** and **SADC** harmonization procedures
- Upgrading RIMS for online operation of all regulatory functions

Conclusion

- We still encourage Indian investors to utilize the existing investment opportunities and incentives to establish pharma and devices manufacturing facilities in Tanzania

- For imported products, we urge you to develop, manufacture and supply good quality, safe and efficacious products to protect and promote health, and above all - safeguard Tanzanian citizens

More details are available at: www.tmda.go.tz



Thank you very much for your attention (Asante Sana)

Bahut (बहुत)

Dhanyavaad (धन्यवाद्)

Shukriyaa (शुक्रिया)

Thaiṅkyū (थैंक्यू)