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Introduction to Tanzania Medical Devices Regulatory System

Medical Devices Sector

Mission

To protect and promote public health by ensuring safety, quality and effectiveness

Vision

To be the leading Regulatory Authority in ensuring safety, quality and effectiveness in Africa.

Tanzania Regulatory Framework

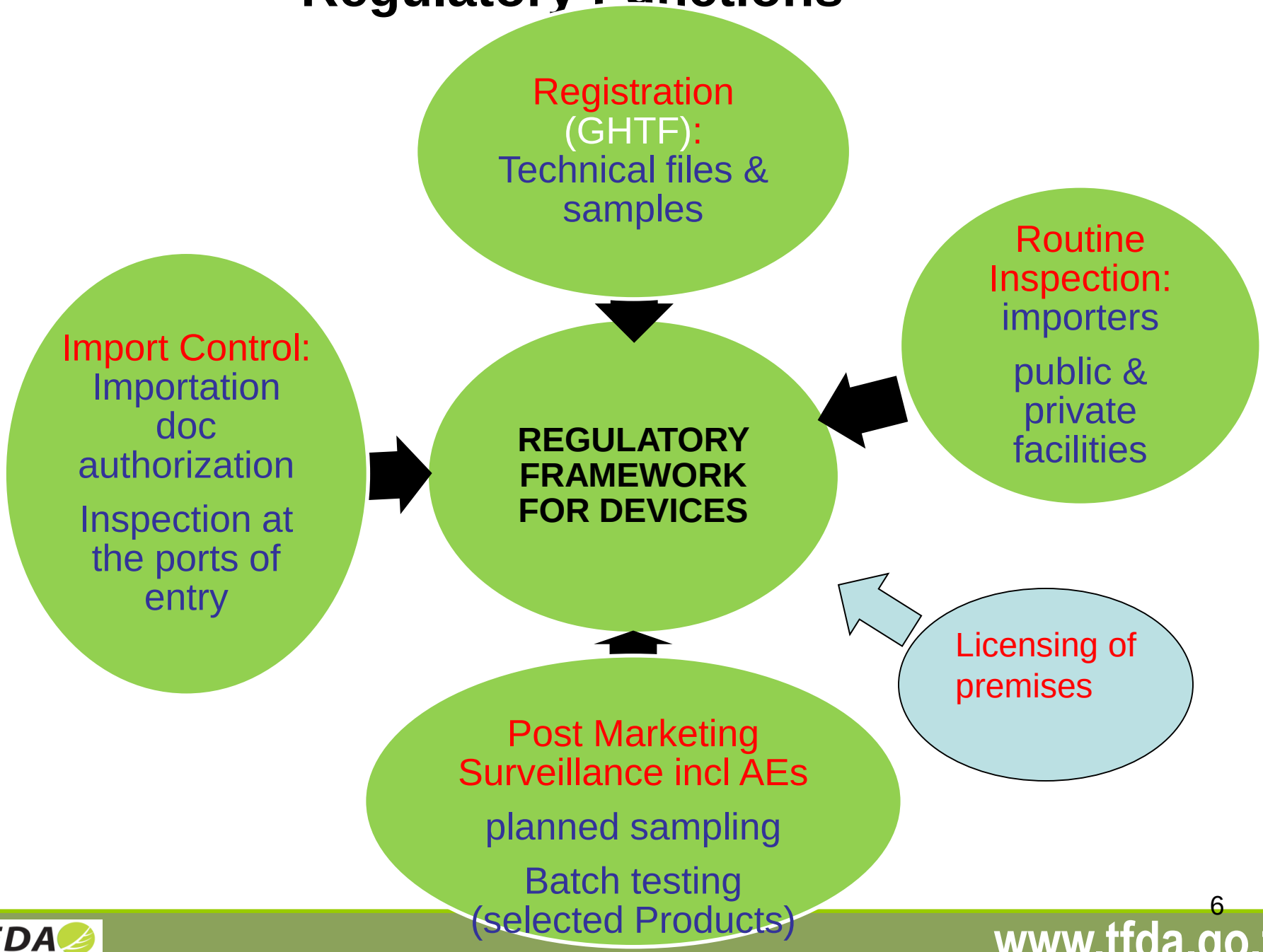
- **Health Policy**
  - The policy directs TFDA to regulate among other products, medical devices and diagnostics.

- **The Act**
  - Provides for regulation of quality, safety and efficacy of food, medicines, cosmetics and medical devices including diagnostics
  - Empowers the Health Minister to make regulations and the Director General to make technical guidelines.
  - Section 5(1) of the Act mandates TFDA to regulate all matters relating to safety and performance of medical devices.

Tanzania Regulatory Framework …

- **TFDA structure and responsibilities**
  - Designated section for medical devices and diagnostics control under the directorate of medical products control.
  - Regulatory functions undertaken
    - Pre-market control-assessment and registration of products
    - Control of importation and exportation (import authorization and inspection at ports of entry)
    - Licensing of manufacturers and importers
      - Quality management system and good manufacturing practices audit.
    - Post marketing surveillance and adverse events monitoring

Regulatory Functions



Regulation Milestones

- **2008**
  - Department of Medical Devices Assessment and Enforcement was formed.

- **2009**
  - Notification of all medical devices on the market.
  - Registration/licensing of premises introduced + Guidelines.
  - Guidelines for submission of documentation for registration of medical devices developed.

- **2010**
  - First Phase of registration introduced for priority 16 categories of devices ranging from classes A – D.

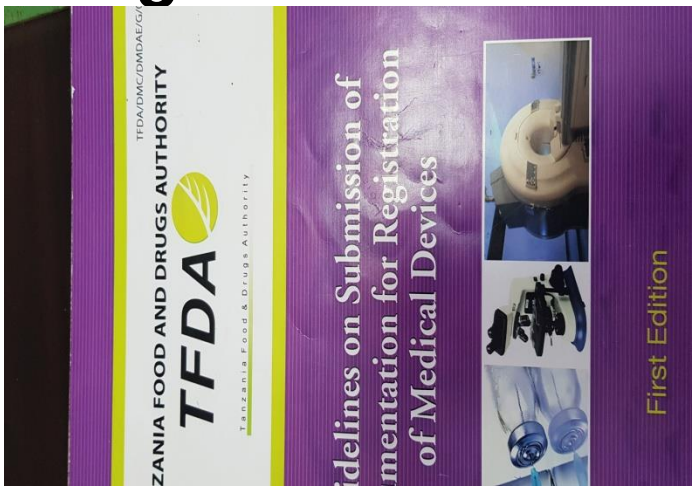
Regulation Milestones…

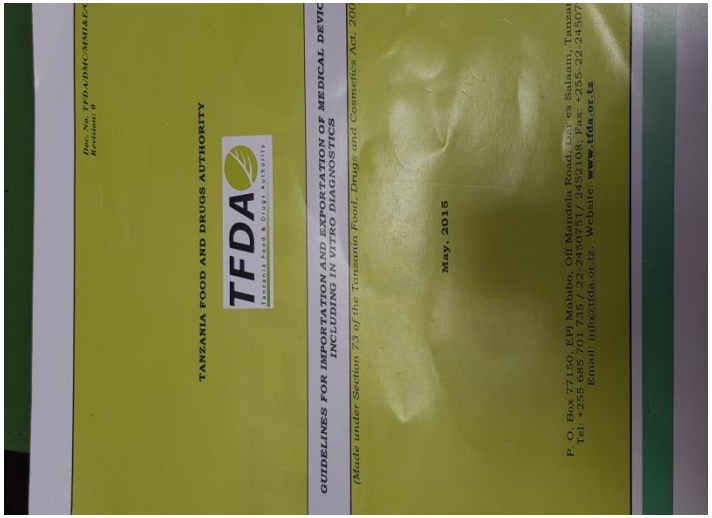
- **2016**
  - Second Phase of registration introduced for all medical devices except Class A non active, non sterile and with no measuring function.
  - Introduction of PMS for medical devices.
  - Introduction of vigilance system.
- **2017**
  - Introduction of Quality Audit (ISO 13485) (Class B-D manufacturing facilities).

Regulation Milestones…

- **2017**
  - Starting Regulation of in vitro diagnostics and laboratory equipment
    - Notification (ended 30th June 2018)
    - Registration, licensing of premises, Import & Export Control, PMS, AEs monitoring

Instruments for Regulation





- Tanzania Food and Drugs Authority (Control of Medical Devices) Regulations.
- Tanzania Food and Drugs Authority (Fees and Changes) Regulations.
- Guidelines for submission of documentation for registration of medical devices.
- Guidelines for submission of documentation for registration of in vitro diagnostics.
- Guidelines for importation and exportation of medical devices incl. IVDs
- Guidelines for medical devices vigilance system in Tanzania.

All documents are accessible on the TFDA website www.tfda.go.tz

Regional and International Participation and Collaboration

- IMDRF
- GHTF
- GMDN
- AHWP/ WG1 and WG2
- WHO/AFRO, WHO/PQ
- AU-NEPAD/ AMRH
- PAHWP
- EAC

Areas of Priority

- Continues to sensitize applicants on adherence to essential principles of safety and performance requirements, labeling requirements.
- Building capacity in assessment of IVD and quality audit.
- Strengthening Post marketing surveillance (risk based surveillance)
- Advocacy on AE and incident reporting.
- Strengthening regional collaboration and cooperation.

Asante, Merci, Thank you