Tanzania Food and Drugs Authority

20TH ASIAN HARMONIZATION WORKING PARTY ANNUAL MEETING

2 – 6 NOVEMBER 2015

BANGKOK, THAILAND

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TFDA

Tanzania Food and Drugs Authority

- TFDA is an Executive Agency under the Ministry of Health and Social Welfare
  - ► established under the Tanzania Food, Drugs and Cosmetics Act, Cap 219 of 2003
  - ►Operates as per Executive Agencies Act, Cap 245 of 1997

- A regulatory body mandated to control safety, quality and effectiveness
  - food, medicines, cosmetics and medical devices (incl. in vitro diagnostics)

- Headquarters in Dar es Salaam & 7 zone/branch offices across the country

TFDA Mission and Vision

- **Mission -** to protect and promote public health by ensuring quality, safety and effectiveness of food, medicines, cosmetics and medical devices.

- **Vision –** to be the leading African Regulatory Authority in ensuring safety, quality and effectiveness of food, medicines, cosmetics and medical devices for all.

- **Quality Policy Statement –** Commitment to quality management systems as per ISO 9001:2008 and ISO 17025 & WHO GLP for the QC laboratory.

Tools for regulation of medical devices

- **Health Policy, 2007**
  - Policy directive for TFDA to regulate among other products, medical devices and diagnostics.

- **Tanzania Food, Drugs and Cosmetics Act, Cap 219 of 2003**
  - Section 5(1)(a) mandates TFDA to regulate all matters relating to safety and performance of medical devices.

- ***Control of Medical Devices Regulations, (Government Notice No.315 of 31 July 2015)***
  - Technical & regulatory requirements for control of medical devices
    - Pre-market control – registration, licensing of establishments
    - Post-Market control – import permits, inspection and PMS (includes AEs)
    - Recall and disposal procedures

Updates

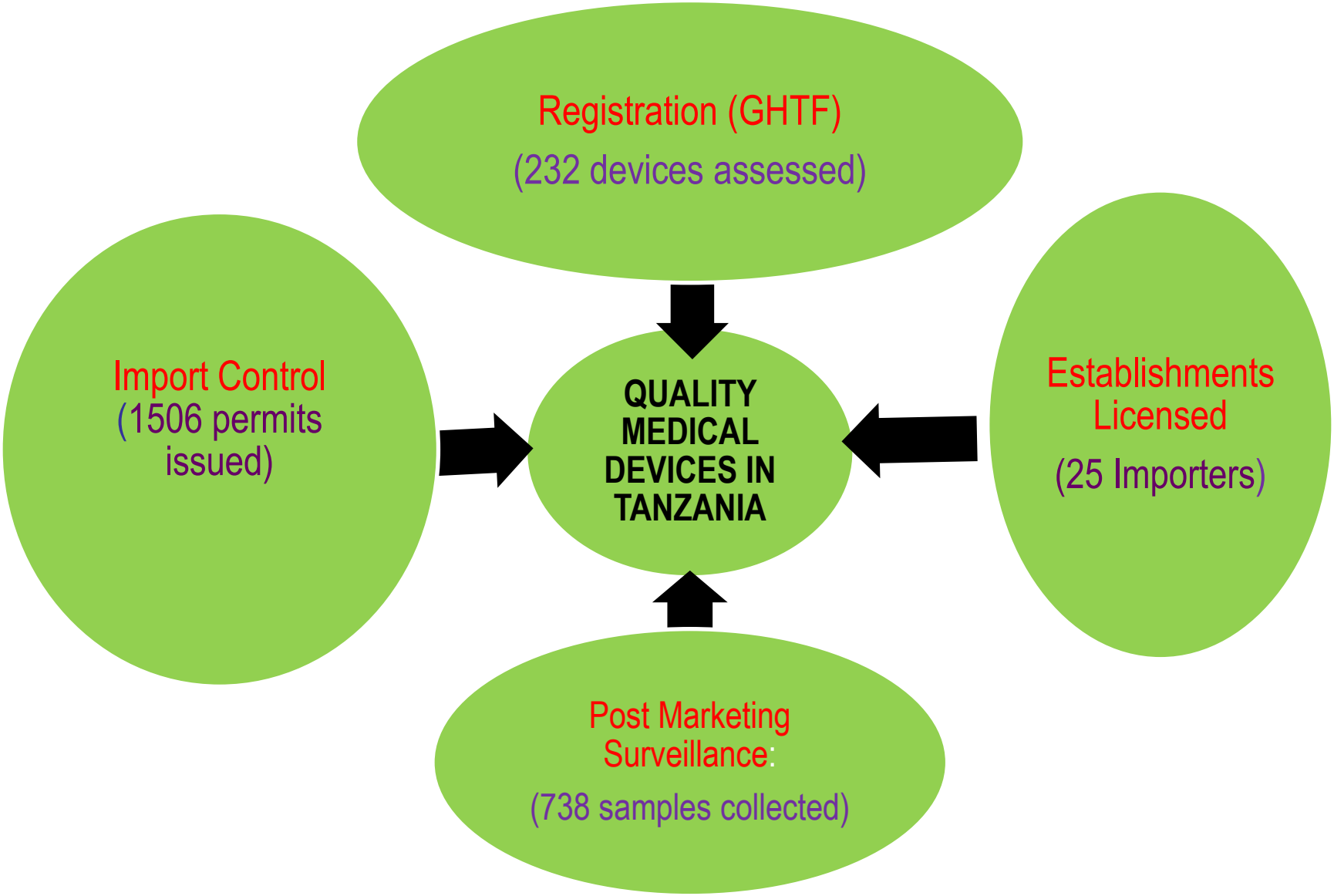
- **2008 -** Department of Medical Devices Assessment and Enforcement was formed
  - Two (2) staff members - *Manager and one officer*

- **2009**
  - Notification of all medical devices on the market
    - list of 3,500 devices, basis for issuance of import permits
  - Guidelines developed
    - Registration/licensing of establishments
    - Submission of documentation for registration of medical devices
- **2010**
  - First Phase of registration introduced
  - Focusing on priority 16 categories of devices ranging from classes A – D.

Updates …(2)

- **2012**
  - Founding Member and Current Chair of the Pan African Harmonization Working Party (PAHWP)
- **2014**
  - Joined Asian Harmonization Working Party (AHWP)
  - New tools – Guidelines on PMS and Import & Export Control
  - Participated in the IMDRF and Health Canada forums on MDs
- **2015**
  - Approval of Regulations for Control of Medical Devices (Government Notice No.315 of 31 July 2015)
  - Joint assessment of IVD files under WHO Prequalification Programme – Capacity building
  - Two (2) staff attached to US FDA for 3 months on assessment of HIV tests

Specific updates for 2014/15



Updates on AHWP work since November 2014

- Joined four (4) AHWP WGs - WG1, WG2, WG4 and WG9;
- Participated in two meetings (teleconferences) organized by WG2;
- Participated in survey of IVDDs regulation;
- Drafting grouping guidelines for medical devices pre market submission under WG1; and
- Joined SADS (Safety Alerts Dissemination System) through WG4 in October 2015.

Lessons learned

- Number of experts considering enormous varieties of medical devices and IVDs and rapidly changing technology.
- Control of imports ~ 100% devices are imported.
- Capacity of the laboratory to test medical devices and IVDs.
- Need to improve working relationship with stakeholders (Government & Industry)
- AHWP a unique platform for emerging regulators
  - Networking and capacity building

Future Plans for 2016 and beyond

- Approval by Parliament of the amendment of the law to provide for effective regulation of medical devices
- Recruitment of additional staff to support control of IVDs
- Establishment of a robust system for AEs monitoring as a component of PMS

Conclusion

- Some progress recorded in putting a system for control of safety and performance of medical devices;

- Gap still exist for effective control of medical devices in Tanzania
  - Explore and utilize available opportunities; and

- Acknowledge continued support from WHO, AHWP, Regulators.