REGULATION OF MEDICAL DEVICES IN TANZANIA: WHAT HAS BEEN ACHIEVED?

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Outline

- Introduction
- Regulatory Framework
- Regulatory systems
- Medical devices testing Laboratory
- Conclusion
Tanzania Medicines and Medical Devices Authority: Introduction

• **TMDA** – Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children

• Established under the Tanzania Medicines and Medical Devices Act, 2013

• The Act;
  • Provides for regulation of quality, safety and efficacy of medicines and **medical devices** *(incl in vitro diagnostics)*
  
  • Empowers the **Health Minister** to make regulations & the **Director General** to make technical guidelines

• Section 5(1) of the Act mandates TMDA to regulate all matters relating to safety and performance of medical devices.
Regulatory system: evolution and key milestones

- **2008 Establishment**
  - 2 staff

- **2009**
  - Notification of all medical devices (3500)
  - MD regulations - Guidelines (3 Staff)

- **2008 - 2010**
  - First Phase of Registration for 16 priority devices
  - Devices Classification
  - 5 Staff

- **2010 - 2012**
  - PMS for IVDs and Devices (5 Staff)

- **2012**
  - Registration of all medical devices
  - Reviewed regulations structured PMS (6 Staff)

- **2015**
  - Registration of all medical Devices
  - 2015

- **2017**
  - Regulation of IVDs - Vigilance (9 Staff)

- **2019**
  - 1549 Registered
  - 5500 low risk Notified (15 Staff)

A decade of regulatory harmonization
A decade of regulatory harmonization
Market Authorization

- Classification based on GHTF rules.

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<tr>
<th>Class</th>
<th>Risk</th>
<th>MA path</th>
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<tr>
<td>A</td>
<td>Low</td>
<td>Notification</td>
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<tr>
<td>B</td>
<td>Low – Moderate</td>
<td>Registration</td>
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<td>C</td>
<td>Moderate – high</td>
<td>Registration</td>
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<td>D</td>
<td>High</td>
<td>Registration</td>
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- Notification: IFU, labelling & samples

- Registration: Device details, Summary of Technical Documentation (STED) and labelling. Quality audits?

- Notification: one time

- Registration: 5 years

Note: IVD regulation in 2017
Import & Export Control

- Requirement: Market Authorization
- Application: Online
- Processing time: 24 hours (csc)
- Permit validity: six months
- Uses: up to 3 partial shipment
- Special permits: compassionate, donations
- POE inspections: against invoice, permit, regulatory requirements
Manufacturers Audit

- Introduced: 2017 (quality audit manual)
- Standard: ISO 13485 and Medical devices regulations
- Sites inspected: 80 (74 passed and 6 failed)
- Desk review: Introduced in 2019 (14 SMFs reviewed, 4 passed, 10 additional data requested)
- Action taken: MA suspended, recalls
- Certificate validity: three (3) years.

- Plant locations: predominantly India and China
- Common observations:
  - certifications without meeting minimum requirements
  - new concept to most manufacturers
  - emphasis on documentation than GMPs
- Issues worth considering:
  - fees structure vs sites and products
  - multinationals with multiple sites: uniform quality systems
  - tailor made trainings for regulatory audits
Post marketing surveillance

A decade of regulatory harmonization

- Pilot 2012-2015
  - Malaria diagnostics (mRDT)
  - HIV (HIV – RDT).

- First Programme 2015-2018
  - IV Cannula
  - Feeding tubes
  - Cotton wool
  - Bandages

- Second Programme 2018-2020
  - Surgical gloves, Surgical suture, mRDT, HIV RDTs
  - Syringes, Sanitary Pads, Baby diapers, Sterile gloves – under analysis
  - Condoms, Syphilis test, IV Cannula – planned for 2019/20
• Initiated in 2016 (MD Vigilance guidelines)

• Sensitization to health workers: 1500+

• Public awareness campaigns: TV, Radio, Posters

• Reports received through:

• Reports received: 142

• Follow up, Investigation and lab testing

• Decision: Product recall, MA withdrawal and Disposal
Medical Devices Laboratory

• Established: 2017
• Parameters: Physical, Sterility
• Activities: PMS samples testing
  Pre-distribution testing (lot to lot)
  Performance evaluation
• Products: Condoms, mRDTs, HIV Kits, Gloves, Sutures, Syringes, Sanitary towels, Cannula
• Minimum regulatory functions can be practically implemented on medical devices and in vitro diagnostics.

• Require tools for regulations and resources.

• Flexibility in adopting the tools will facilitate effective regulation.

• Risk based: in all functions. Value on Investment.

• Work sharing and information exchange: catalyst for advanced systems.
Thank you