Regulation of Medical Devices: Tanzania Experience

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Key milestones

⟶**1999:** Control of importation started under Pharmacy Board.

→ **2003:** TFDA was established

→ **2008:** Department of Medical Devices Assessment and Enforcement created

→ **2009-2010:** Notification of all devices on the market started **(3,500 devices notified)**

→**2010:** 1st phase of registration started and still on going.

→**Up to 2013:**114 devices registered

Regulation of medical devices

- Some class A Devices are exempted from registration e.g adhesive,bandages,clip e.t.c
- Any other class A device not in exempted list has to be registered.
- All devices in class B,C and D needs to be registered
- PMS started-collect samples of syringes,condoms and gloves and test them at TFDA lab.

The evaluation process for registration of devices is done in two stages:

- Screening
- Evaluation

List of devices under 1st phase of registration

- Syringes-autodisable
- Surgical sutures
- Examination & surgical gloves.
- Scalp vein set.
- Intravenous cannulae.
- Catheters and tubes.
- Prosthetic replacement.
- Condoms.
- Needles.
- Administration set.
- Blood collection bags
- Surgical dressings.
- Drug eluting stents and intraocular lenses.
- Orthopaedic implants.

Current status of medical devices regulation

Phase I	Phase II	Phase III
Control of importation Ongoing . Development of guidelines: •Registration of Devices •Licensing of Premises •Good distribution Practices •Post Market Surveillance. Completed	Registration of Medical devices-Started on 2010 still ongoing . Licensing of premises dealing with medical devices-ongoing. Advertisement and promotion control –Not yet started.	Prohibition against unlicensed premises dealing with medical devices –Enforcement ongoing. Prohibition against supply of unregistered medical devices-Partial enforcement has started for devices which have been registered.

Challenges

- Inadequate expertise within TFDA to cope up with Increase number of devices along with varying technologies and complexities → need for capacity building and networking.
- Few quality control laboratories within the regions for testing devices-TFDA capacity is limited.
- Limited reference documents e.g. packaging guidelines,devices co-packed with vaccine.
- Regulation of devices and combined delivery device not done parallel.
- Lack of medical devices regulatory system in neighbouring African countries.

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