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

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