

SAAPI

South African Association of Pharmacists in Industry

MEDICAL TECHNOLOGIES - REGULATORY UPDATE – SA and SSA

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16 May 2019*

Update

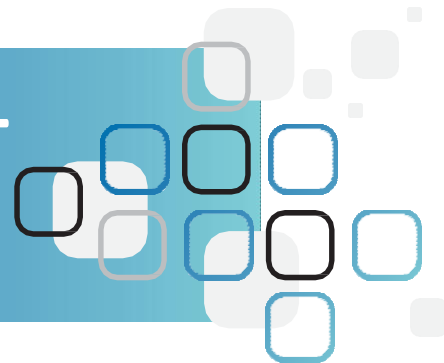
- South Africa – Regulatory Implementation and Roll-out Status
- South Africa – Industry Response and Actions

- Africa – Regulatory Implementation and Roll-out Status
- Africa – Industry Response and Actions



- Licence Backlog
- Amendments
- Wholesalers

Establishment Licence –
Section 22



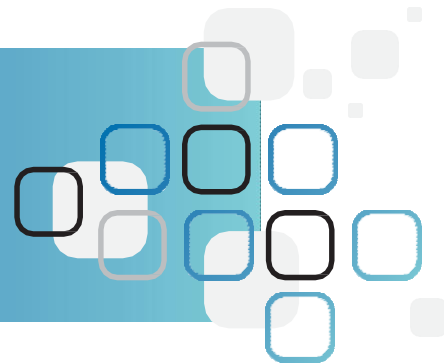
- AR Designates
- Formal Communication as a policy paper

**Authorised Representatives at
Sub-Sites**



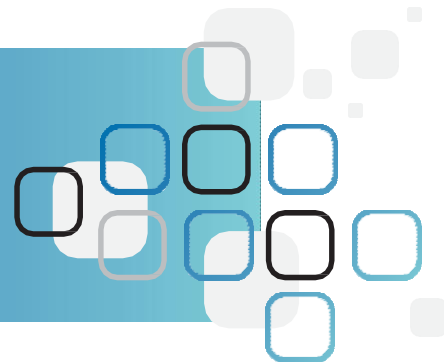
- Labelling activities
- To align with ISO13485 when applicable (?)

**Definition of a
Manufacturer**



- Restriction on the advertising to the public of Class C and D medical devices
- Feedback – SALDA and SMASA and other
- Access to Medical Device and IVD Guidelines

Advertising



- Comments were submitted to the draft guideline
- re-submitted

Borderline Medical Devices



- Capacity, structure
- Licensing timelines

Radiation Control



All AE's (FSCAs FSNs Recalls) :

All Field Action and Recalls

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Adverse Event Reporting



- ISO 13485
- Guidelines to be developed

Quality Management System



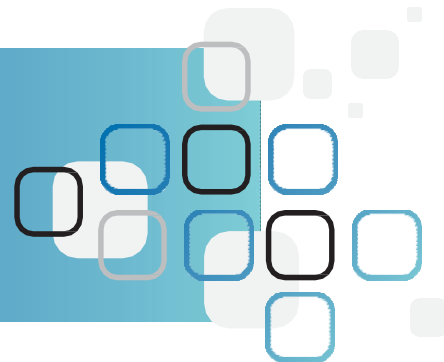
- Only licensed entities to qualify
- SAHPRA to communicate with Procurement Entities
- Industry to assist
- Publication of a list of Licensed Companies

Tenders and Government Procurement



- Technical Dossier guidelines
- Call-up/Roll-up Plan
- Fees
- Notice/Compliance/Transition Period

Medical Device Product Registration



AFRICA UPDATE

Ethiopia

Ghana

Kenya

Nigeria

Tanzania