SAAPI

South African Association of Pharmacists in Industry

MEDICAL TECHNOLOGIES - REGULATORY UPDATE – SA and SSA

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Becton Dickinson (BD)
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

Advertising

- 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

- Comments were submitted to the draft guideline

- re-submitted

Borderline Medical Devices

- Capacity, structure

- Licensing timelines

Radiation Control

Adverse Event Reporting

All AE's (FSCAs FSNs Recalls) :	All Field Action and Recalls
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- 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