SAHPRA
South African
Health Products
Regulatory Authority

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PMS: FSCA/FSN/CAPAs

An agile and responsive African health products regulator that is globally recognised as an enabler of access to safe, effective and quality health products in South Africa.

To promote access to health products and protect human and animal health in South Africa through making science-based regulatory decisions.

Ubuntu
Transparency
Responsiveness
Efficiency
Integrity
Excellence

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About Us

Safety, Efficacy & Quality

Regulating (monitoring, evaluating, investigating, inspecting and registering, PMS) all health products.

incl **medical devices and in vitro diagnostics** (IVDs)

Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

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Situation

- Medical Device (IVD's and Non-IVD's) industry existence = Yrs
- Less than 5 years ago: Implementation of Requirements (as in the ACT)
- Regulation published (now comments under final review for new version publication)
- Guidelines are published
- Issued licenses to 2600 applicants to date (2017 -

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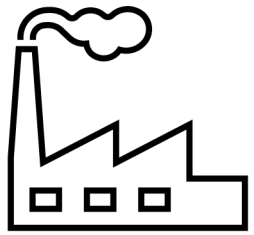
Establishment license

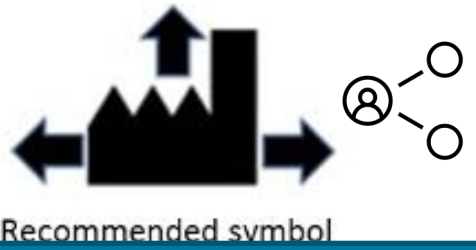
- Establishment license to



Manufacturer

Wholesaler

Ensure compliance to requirements
Including having QMS in place = traceability/PMS



Distributor

Import/Export

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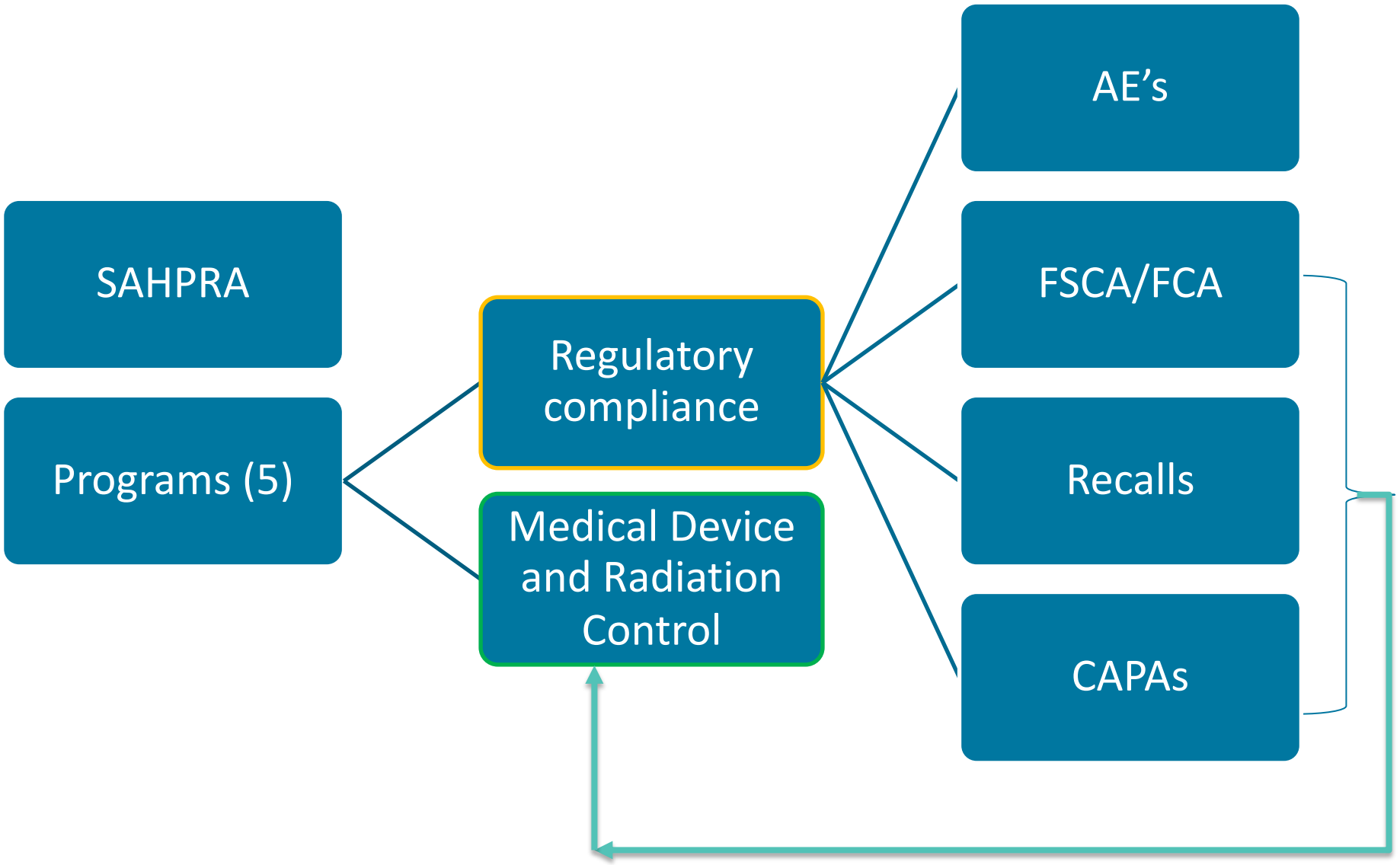
FSCA/FCA/CAPAs



- New process/new unit integration
- Regulation aligned to MDs/IVDs
- Understand the industry
- Guidelines = for alignment
- Resource availability = Focused activities

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Current processes

- 2 units work in collaboration
  - AE's = >30
  - FSCA = 7
    - Proper infrastructure in place (pre-planning)
      Resource allocation defined
      System (IT – manual/online)
    - Industry engagement is required
    - Training /workshop requirements
- Surgency of Covid-19: increased number of complaints = related SF products= Masks
- Increased AE's reporting
- Monitored tracking system developed

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Q & A

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Thank You

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