For A Healthier Africa
AFRiSUMMIT
2nd - 5th November 2025
Hilton Grand Nile Hotel, Cairo - Egypt

MEDICAL DEVICE REGULATORY : SA

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AGENDA

INTRODUCTION: SAHPRA

Vision

- 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.

Values

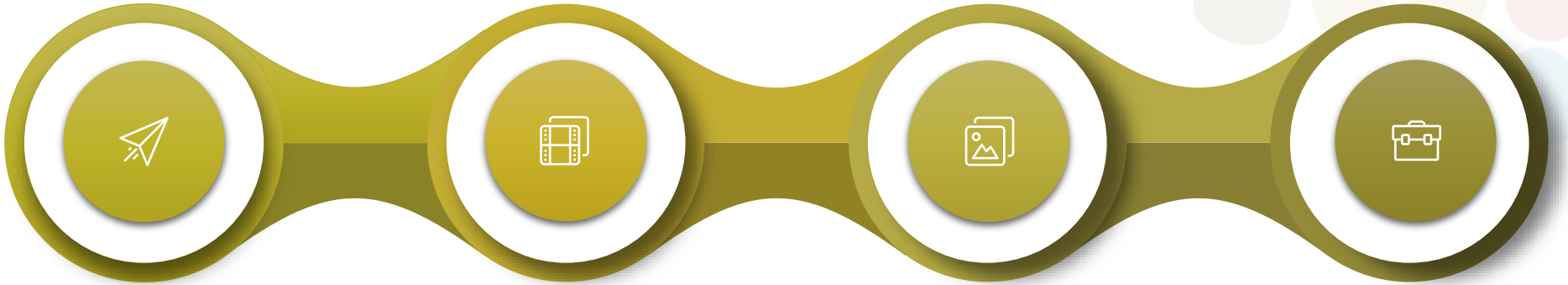
- Ubuntu
- Responsiveness
- Integrity
- Transparency
- Efficiency
- Excellence

Mission

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

MEDICAL DEVICE REGULATORY

MD regulatory -Phase one.



Year 2015

Policy (Act) (MRSA) update.

Year 2016

Medical Device(MD) and IVD Regulation publication

Year 2017

- MD Guidelines publication
- Establishment licensing: Manufacturers, Importers, Wholesalers

Year 2022

MD Establishment license renewal issued

Manufacturers

Importers

Year 2015 | Year 2016 | Year 2017 | Year 2022

BASIC LEVEL OF CONTROLS & ENFORCEMENT

Premarket	Placing on market	Post market
❖Publish laws, including definition and regulations , transition period ❖Establish medical device classification for regulatory process ❖Establish Essential principles of MD for safety and performance ❖Establish basis for reliance recognition ❖Establish requirements of declaration of conformity ❖Establish requirements for manufacturers for QMS ❖Requirements for labels & labelling ❖Prohibit deceptive, misleading & false advertising ❖Establish provisions for exceptional premarket situations	❖Licensing of establishments ❖Listing of medical devices ❖Import controls	❖ Establish system for vigilance ❖ Require mandatory notification by manufacturer for FSCA ❖ Establish a procedure to withdraw unsafe medical devices from market ❖ Establish procedure to issue safety alerts to users ❖ Undertake market surveillance

PRODUCT REGISTRATION FEASIBILITY STUDY(PRFS)

Preparation for Phase two (Registration/MA).

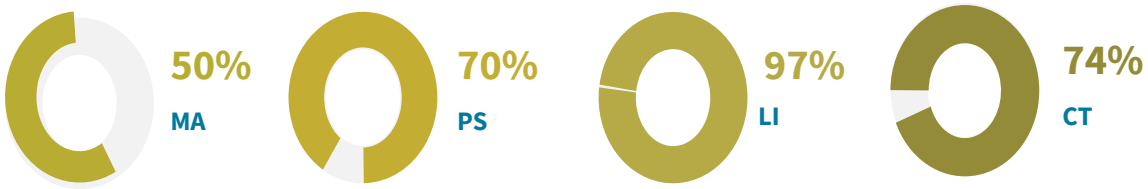
- Publication of EoI and drafted working guidance docs
- Acceptance of interest parties to the study
- Submission of technical dossier for review.
- Review of technical dossier.
- Outcome of review shared with participants.

REGULATORY SYSTEM

Phase 2: Not started

Regulatory systems implementation analysis

Percentage implementation of each regulatory system



Other Regulatory Systems

Regulatory systems to support Phase 1 and 2.

Accreditation of CABs

South African Accreditation System: SANAS

ASANAS SAHPRA &SAHPRA : MoU

ISO 13485 accreditation for CABs

Recognition of CABS

SAHPRA recognizes accredited CABs

ISO 17065 Scheme

Developing Scheme to accredit and recognize for ISO 17065 (technical dossier review).

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THANK YOU