

SAAPI Presentation

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Medical device regulation – an update and roadmap for the future

Mission, Vision and Values

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

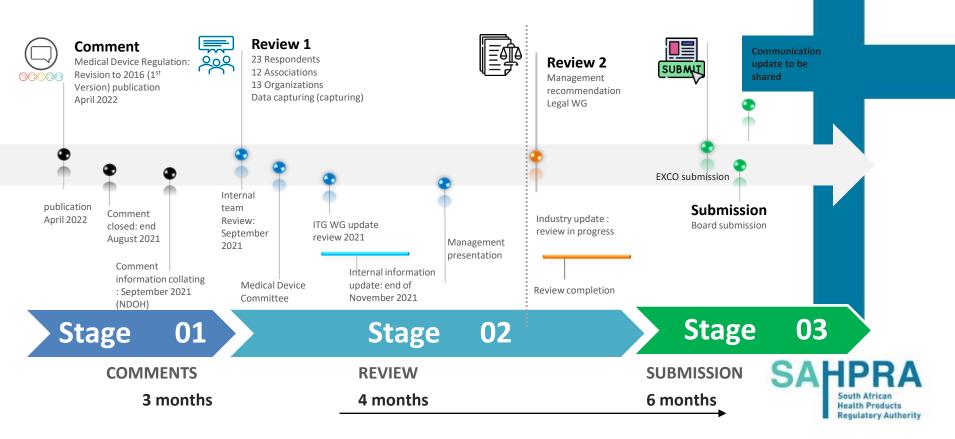
Mission

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





Medical Device Regulation update



Current activities of Note

- Five (5) year Establishment Renewals
- Timelines is important
- Contravene : Section 22 C of the Act
- Continuous engagement
 - Regulations
 - Workshops
 - Publications
 - Meetings



Intention **Product** Registration **Product call-up: Transitional process** Pilot trial: considered Prep work: (Isolation) Resource Capacity: Human Resources/Training/IT infrastructure (licensing/product registration)/ Stakeholder engagement/Fees structure Guideline (s) publication publication/Reliance method Clinical trials, Fees, technical dossier, labelling, Post-marketing Surveillance reporting

Regulations: published for implementation



Stakeholder Management

Forging Partnership Regional Engagement: **General Stakeholders** Industry Experts engagement Africa Medical Device **Regulatory Authorities** Forum ANVISA SADC member Legislative Academic institutions document: Act (Regulatory Agency) Scientific US FDA Media Medical Device . Co-Chair of AMDF organizations SWISS Medic General Public Regulations (Africa Medical Healthcare Health Singapore End user Device Forum) - Workshop (initiator) professional (HSA) Active participant and participants) • WG - WHO; FIND/TB Technical working Government entities Guidelines Review groups (e.g., Trade and Guidance documents Participate as part industry) of WG Applicant meetings





THANK YOU