SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Regulatory update: Long term goals and objectives

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SAHPRA
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- SAHPRA as a enabler
- Lessons from COVID-19 pandemic response
- Integrating learning into SAHPRA business as usual

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As we aim to be an effective regulator, we aim to ENABLE access to safe, effective and quality medicines and health products

Accelerating access to safe and effective drugs

- Accelerated application of **digital technologies** to enable reduction of turn around times to attain goals as per 5 years strategic plan
- Have **clear metrics/KPIs** that enable the strategic goals and communicate SAHPRA's strategic intent to the public
- Enabler of product registration and regulation through improved time frames **in support of Universal Health Coverage under NHI**
- Partner with relevant stakeholders to educate the public through **public awareness campaigns**
- **Support and align with the SA policies** to grow the health sector and access to health products

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1. Enabler of **accelerated access** to safe and effective health products such that no South African suffers health burden when drugs exists
2. **Enabler of innovative product development and access**
3. **Enabler** of local health **sector growth**

Supporting innovative product development and internal innovation

- **Thought leader** in the Health Sector
  - Provide access to the latest information on cutting edge advances in the sector
  - Collaborate with KOL/SAHPRA external experts to provide trusted information
  - SAHPRA website to be a trusted source of information
- **Create a culture of innovation**
  - Align with global best practices
  - Improve internal processes through utilizing already existing innovative tools and building new tools

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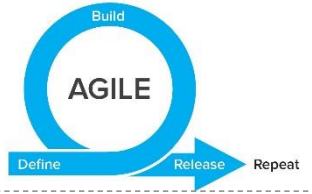
SAHPRA Learnings from COVID-19 response

OPEN TO LEARN from other regulators and apply what is relevant for the local context

COLLABORATIVELY engage stakeholders that support the availability of data to enable making science based decisions

Efficient regulator

AGILITY and URGENCY in regulatory processes to accommodate rapid pace of change



STRIGENT, science based regulatory decisions to ensure the safety of the public

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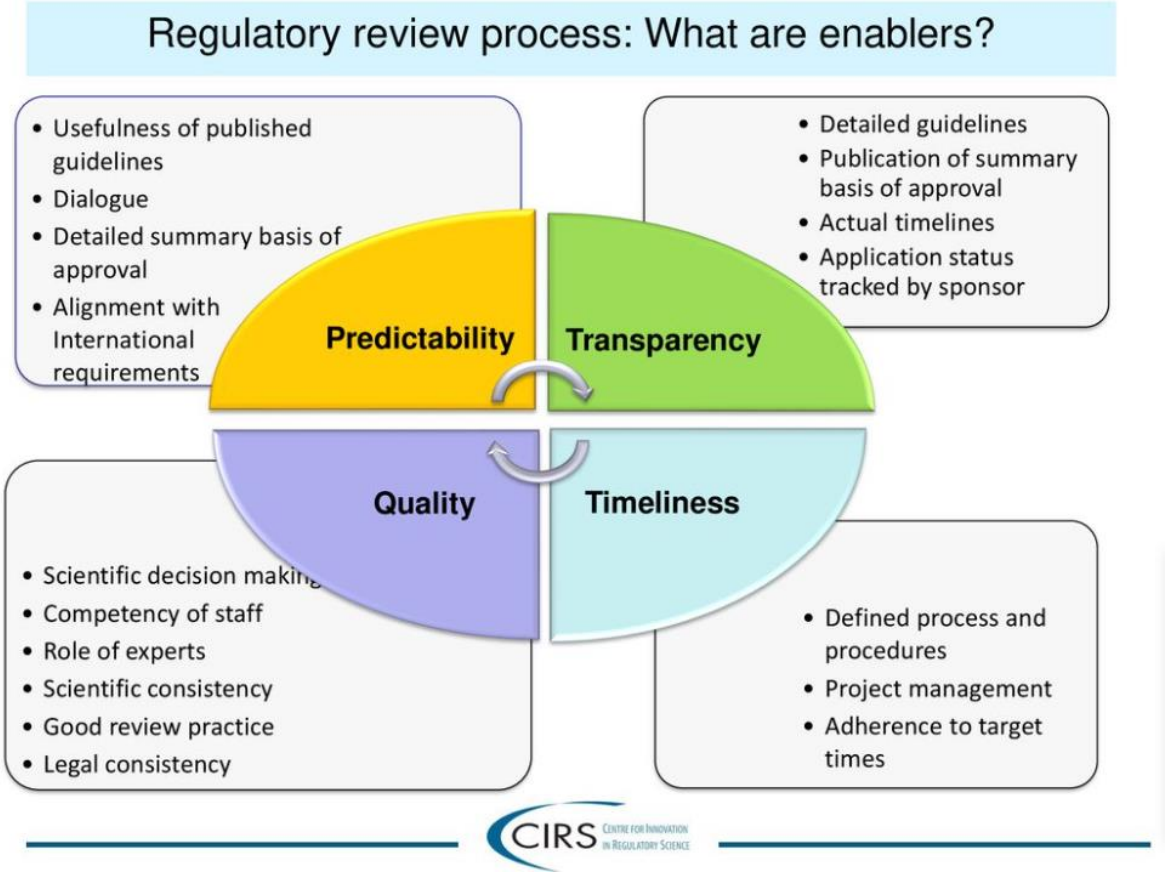
Open to **learning**



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SAHPRA has embraced **collaborations**

National

- Local Universities and Science Councils
- National Institutions of Health

Regional

- Member of SADC Zazibona - Evaluation
- Member of SADC MRH - Harmonisation

Continental

- Member of AVAREF – Clinical Trials

International

- Member of WHO PQ - Evaluation
- Member of PICS to allow for sharing of GMP – inspection reports
- Member of ICMRA
- Member of the IMRP – Generic applications
- Member of IMDRF – Medical devices
- Observer status of EDQM and USP - Quality
- Observer status of ICH & VICH - Guidelines

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Agility will be critical to enable accelerated access to health products

ELSEVIER

Clinical Therapeutics

Volume 43, Issue 1, January 2021, Pages 124-139

Review

Regulatory Agilities in the Time of COVID-19: Overview, Trends, and Opportunities

Winona Rei Bolislis MA, Maria Lucia de Lucia, Felipe Dolz DVM, PhD, Runyi Mo MSc, Makoto Nagaoka PhD, Heraclio Rodriguez MBA, May Li Woon MPharm, Wei Yu MSc, Thomas C. Kühler PhD

1. Regular communication with the public
2. Process improvements and regulatory frameworks for Public Health Emergencies
   - Expedited evaluations
   - Emergency Use Authorization for
   - Clinical trial requirements
   - Enhanced collaborative review pathways

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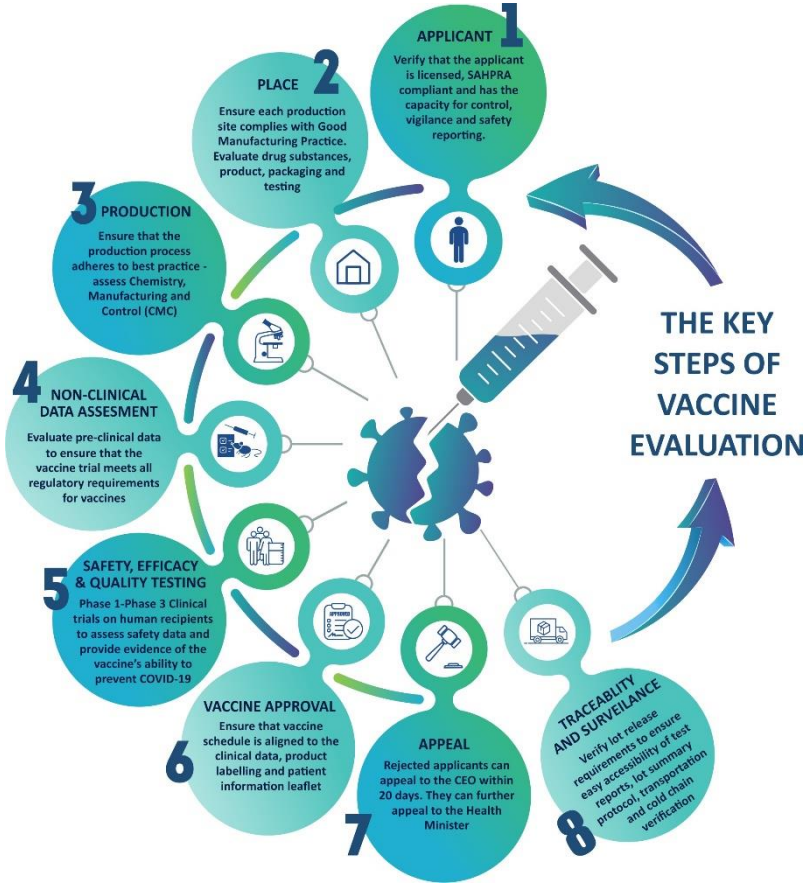
The regulators will remain **stringent**



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Thank you