



SAHPRA

South African
Health Products
Regulatory Authority

- WCBP Symposium
- Washington, DC, USA, 27-29 January 2026
- Overcoming Barriers to Local GMP Manufacturing and Testing in LMIC's

MPHAKO BRIGHTON RATLABYANA

**MANAGER PHARMACEUTICAL EVALUATIONS
(PRE-REGISTRATION UNIT)**

mphako.ratlabyana@sahpra.org.za
ratlabyanamb@gmail.com



South African Health Products Regulatory Authority (SAHPRA)

- Population ~ 62 million
- HQ in Pretoria-Capital city
- 2 Regional offices (Durban and Cape-Town)
- ~400 staff members



South African Health Products Authority (SAHPRA)

1

PFMA Schedule 3A
Public Entity

- Autonomous entity
- Operates independently

2

Entity of National
Department of Health

- Previously **Medicines Control Council** within the National Department of Health. (Since 1965)
- 8th year of operation as a schedule 3A public entity

3

Governance
structures in place

- Accountable and reports to the **Minister of Health and Parliament** through the **SAHPRA** board
- The board is appointed by the Minister
- The board has a governance and strategic oversight role

4

Mandate: Safety,
Quality, Efficacy and
Performance

- Regulates all health products for human and animal use
- Performs 9 Regulatory functions as per WHO GBT (**ML3 vaccines**
ML4 Lot Release, RCORE vaccine regulations)

2025/26 – 2029/30 STRATEGIC PLAN



Applying global standards of Good Review Practices



Applying reliance on a risk-based approach



Working towards being a member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)



Becoming a World Health Organization Listed Authority (WLA)-Currently ML3 for vaccines

WHY SAHPRA IS ENABLING LOCAL MANUFACTURING OF HEALTH PRODUCTS

Strengthening sustainable access to quality, safe and affordable medicines

Enhancing health system resilience through local production

Alignment with African continental strategies (PMPA, PAVM, PHAHM)

Lessons from COVID-19 highlighting import dependency risks

Building long-term self-sufficiency and security of supply

SAHPRA SUPPORT TO LOCAL MANUFACTURING

SAHPRA SUPPORT TO LOCAL BIOMANUFACTURING

01 Routine Inspections

Risk based inspection with priority given to local sites

02 Priority Review Policy

Assessments and registration of Medicines and vaccines that treat serious diseases and is of major public interest.

03 Policy position on enabling local manufacturing

Prioritize inspections, assessment and testing of locally produced products.

04 Alignment with international standards (PIC/S, ICH, WHO)

Reduce country specific requirements.
Recent emphasis on ICHQ7

05 Risk-based testing policy for Lot Release testing

Expedited release process

06 Capacity Building and Presubmission consultation meetings

Internal and external capacity building for inspectors and assessors with partners.
SAHPRA chair GMP TC and Subcommittee on vaccine.
SAHPRA offer applicant opportunity to consult experts during research and development to prevent pitfalls

FACILITATED REVIEW PATHWAYS WITHIN RELIANCE MECHANISM

WHO Collaborative Registration Procedures (CRP)-Active-90 Working days

- Prequalification
- SRA
- CRP lite

Swiss-Medic Marketing Authorization for Global Health Products Work-sharing Procedure (MAGHP)- Active-90 Working days

- MAGHP Full procedure
- MAGHP light procedure

Unilateral, Partial and Internal reliance Mechanisms-Active-200 Working days

- Based on MOU/NDAs (Reference agencies: US FDA, MHRA, EMA (EU NRAs), TGA, Health Canada, PMDA, Swiss Medic and WLA agencies)
- CEP /CPQ (APIs)
- Internal (APIs ,FPPs and BEs)-based on previous SAHPRA approvals

Zazibona collaboration registration procedure (SADC)-Active-90 Working days

- Zazibona

AMRH Pilot (AUDA-NEPAD)/African Medicine Agency (AMA)-Active-90 Working days

Egyptian Drug Authority work-sharing procedure-EOI Published

EU-m4 all-Active

ADDRESSING REGULATORY BARRIERS

Policy Support for Prioritization of local Manufacturing

SAHPRA prioritizes:

- **New applications for locally manufactured vaccines and biotherapeutics**
- **Type II Variation applications** for local site inclusion
- Priority review applies to manufacturers meeting local criteria *without additional fees.*

Reliance-PIC/S, Bilateral Information Sharing

Pre-submission meeting

Impact:

- Faster regulatory decisions support **accelerated market entry**
- Encourages global and local investment in manufacturing capacity



TESTING & LOT RELEASE STRATEGIES

Testing & Lot Release (Regulatory Priorities)

- SAHPRA emphasizes **lab access and product testing** as part of regulatory functions.

Local Testing Prioritization:

- Local testing sites should be empowered and accredited

Benefits:

- Speeds up availability of quality products in market

REGIONAL CENTRE OF REGULATORY EXCELLENCE (RCORE)

In 2023, AUDA-NEPAD designated SAHPRA as a **Regional Centre of Regulatory Excellence (RCORE)** for vaccine oversight.

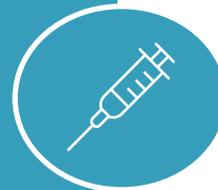


Role of RCORE:

Support **capacity building across African NRAs**

Provide **training, exchange programs & hands-on mentorship**

Strengthen continent-wide regulatory **Harmonization**



CAPACITY BUILDING & TRAINING

Strategic Capacity Initiatives

- RCORE promotes **training in core regulatory functions**
- Skills transfer through **practical exchange programs**
- Focus on:
 - GMP inspection competencies
 - Quality control and laboratory processes
 - Lot release procedures and standards

Outcome:

- Enhanced regulatory workforce can enable:
- Better local oversight of GMP manufacturing
- More efficient quality testing supply chains

Regional, Continental and International Regulatory Partnerships and Engagements



Bundesinstitut für Impfstoffe
und biomedizinische Arzneimittel





Acknowledgement to:
Karin Duxbury-Quality Assessor (Pre-registration Unit)
Khuliso Mathata-Lot release Assessor (Biological Unit)