DEPARTMENT OF HEALTH
Republic of South Africa

SAHPRA
South African Health Products Regulatory Authority

SAHPRA UPDATE

SAPRAA

13 April 2018

Background

The Medicines and Related Substances Act, 1965 Amended

- Act 72 of 2008: **Establish SAHPRA**
  - 3 A Public Entity
  - Extended the mandate to include Medical Devices
  - Enacted: 01 June 2017, this also enacted Act 14 of 2015
- Act 14 of 2015:
  - Appointment of a Governance Board
  - Expand oversight of Medical Devices to include *IVD*'s
  - Address transitional arrangements from MCC to SAHPRA
    - Work of the MCC
    - Staff
    - Assets and contracts
- General Regulations published : 11 August 2017

Background

SAHPRA Vision

To strive towards excellence in health product regulation with the aim of promoting and protecting human and animal health in South Africa, being recognised and respected both nationally and globally as a leading and exemplary health product regulator.

SAHPRA Mission

To safeguard the health and wellbeing of all who live in South Africa and to support human and animal health through scientific and ethical regulation of medicines, medical devices, radiation emitting devices and radioactive nucleides.

SAHPRA Values

Ethical Conduct, Unity of Purpose, Service Excellence, Transformation, Innovation, Integrity.

Background

SAHPRA is responsible for:
monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest. SAHPRA will:

- have **full-time in-house capacity** to support product review & approval and oversee all regulatory functions
- establish **cooperation and information** sharing with other NRAs to support implementation of best practices and timely approval of products

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Status of SAHPRA

SAHPRA
South African Health Products Regulatory Authority

SAHPRA Board members appointed by the Minister - 09 October 2017

- Board consists of 15 members
- Skills of the Board identified in the Act
  - One person each: Law, governance, finance, HR, IT
  - 10 members: medicine, medical devices & IVDs, vigilance, GMP, clinical trials, public health or epidemiology

Board introductory meetings - 24 November 2017, 13 December 2017 and 15 January 2018

SAHPRA Board Members

PROF HELEN REES
CHAIRPERSON

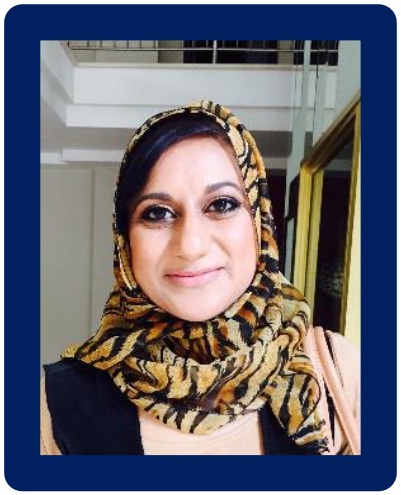
MS M HELA
VICE CHAIRPSERON

SAHPRA Board Members

PROF SHABIR BANOO

PROF AMES DHAI

DR THAPELO MOTSHUDI



ADV HASSINA CASSIM

PROF JEFFREY MPHAHLELE

MS LESIBANA FOSU

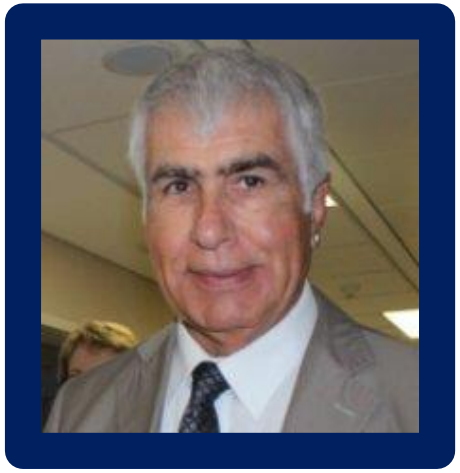
SAHPRA Board Members

DR USHMA MEHTA

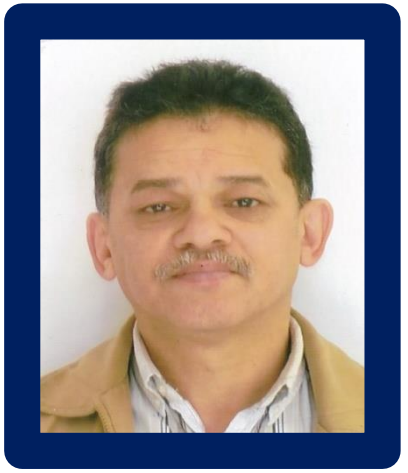
DR EDITH MADELA-MNTLA

PROF KELLY CHIBALE

Mr Norman Baloyi
Dr Mphane Molefe



PROF C HOUSEHAM



DR HENRY LENG

DEPARTMENT OF HEALTH
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SAHPRA
South African Health Products Regulatory Authority

Minister

SAHPRA – Section 3A public entity

BOARD

Acting CEO

Board Exco & Board Committees

Authority

Advisory/Technical Committee

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Status of SAHPRA

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- Minister called for 1st meeting of the Board - 01 February 2018
  - MCC ceased to exist with 1st Board meeting
  - Board Induction - 02 February 2018
  - Board appointed Acting CEO after consultation with the Minister of Health
  - Board appointed committees to assist with work of the Board – S2H
- DOH staff transfer
  - Section 197 transfer
  - Staff component - 207

Status of SAHPRA: Board Committees

- IT & Communications Committee

  Mr N Baloyi

- Human Resource & Remuneration Committee

  Prof J Mphahlele

- Finance Committee

  Ms L Fosu

- Audit, Risk & Governance Committee

  Prof C Household

- Technical Operations & Regulatory Strategy Committee

  Prof S Banoo

Status of SAHPRA

- Board Committee TORs
- SAHPRA policies
- MoU with National Department of Health: Corporate support in the interim (IT, HR, Finance, Supply Chain, Communication etc)
- Key critical posts :

  Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, Board Secretary , Director: Human Resource Management, Director: Information and Communication Technology

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Status of SAHPRA

SAHPRA
South African Health Products Regulatory Authority

- The technical/advisory committees continue for 6 months
- Advisory Committee of chairs established for a period of 6 months
- Re-engineering of regulatory processes (Project Office)
- Strategies to address Backlog
- Fee structure under review
- The 1st SAHPRA Strategic Plan and Annual Performance Plan - tabled in parliament for review in April 2018

SAHPRA Technical Committees

- Complementary Medicines Committee – Dr N Gower
- GxP Committee – Ms J van Oudtshoorn
- Clinical Committee – Prof B Hoek
- Clinical Trials Committee – Prof P Ruff
- Pharmaceutical and Analytical Committee – Dr H Leng
- Biological Committee – Prof N Mbelle
- Legal Committee – Ms S Putter
- Veterinary Committee – Dr V Naidoo
- Medical Devices Committee – Ms S Moodliar
- Names & Scheduling Committee – Mr A Gray
- Pharmacovigilance Committee - Prof M Blockman

Technical Working Groups

- Regulatory Harmonisation/Convergence (A Gray)
- Human Reproduction (B Hoek)
- Expedited /Priority Review (B Hoek)
- Orphan Drugs (J van Oudtshoorn)
- Medicinal Cannabis (S Banoo)
- African Traditional Medicines (E Madela-Mntla)
- Colistin and AMR (A Gray)
- Clinical Trials Policy (P Ruff)

SAHPRA Strategic plan

Strategic outcome oriented goals:

- Goal 1: Publicly demonstrate **responsiveness and accountability** as an effective and efficient high performance organisation.
- Goal 2: **Timeous regulatory decision** taken on medicines and medical device applications to ensure compliance to defined standards of quality, safety, efficacy and performance.
- Goal 3: **Re-evaluate and monitor medicines** and medical devices periodically.
- Goal 4: Investigate, monitor, analyse, solicit and act upon existing and new adverse events, interactions, information with regard to **post-marketing surveillance and vigilance.**

SAHPRA Strategic plan

Strategic outcome oriented goals:

- Goal 5: Ensure **regulatory compliance** through a process of active Inspections and investigations.
- Goal 6: Evaluate **clinical trial** protocols in accordance with defined standards.
- Goal 7: **Evaluate** the applications for sale of **unregistered health products** in accordance with defined standards.
- Goal 8: Establish and strengthen **collaborative initiatives with any other regulatory authority** or institutions in order to achieve the objects of the Medicines Act.
- Goal 9: SAHPRA is capacitated by adequate, competent and motivated **Human Capital**

Envisaged Changes

- Capacity building - Increasing In-house technical capacity
- Expanding technical and administrative staff numbers
- Improving skills base for newer, emerging technologies
- Overhaul peer review system – frequency of meetings
- Specialised areas - retainer system for experts
- Strengthen in-house capacity to respond to new work areas
- Reorganise appeal process to ensure speedier outcomes
- Strengthen cooperation with recognised regulatory authorities
- Backlog project
- Website improvement and strengthening communication through a dedicated unit
- Frequent engagement with stakeholders

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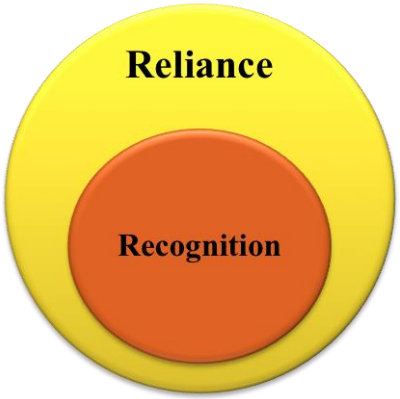
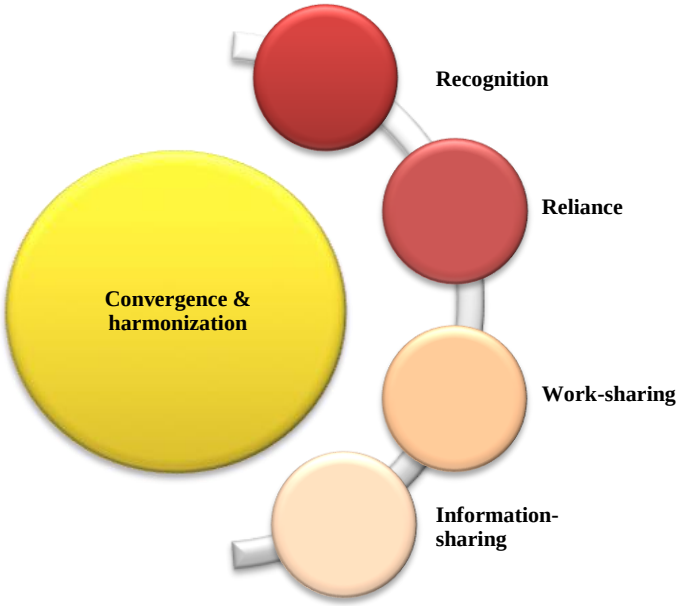
Application of Reliance Models

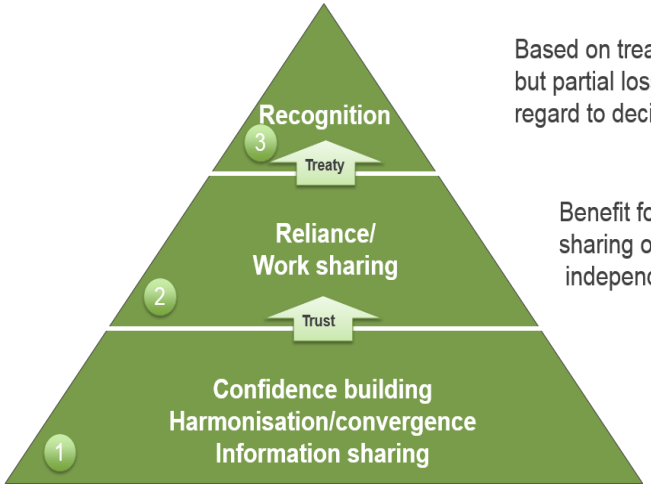
- No longer a question of ‘if’, but when and how
- Taking place even amongst most resourced and mature regulatory agencies; about smart regulation and investment
- Flows from principles of Good Regulatory Practices
- Driven by harmonisation of requirements and understanding of processes of reference regulatory agencies, transparency and trust.
- Abridged methods that avoid duplication of effort – Reliance mechanisms
- Joint review and co-evaluation of applications
- Amended Medicines Act enables work-sharing and recognition of work done by other recognised regulatory authorities

Reliance and Recognition

Doing locally what nobody is doing/can do for you (added value)







Based on treaties; «maximal benefit» but partial loss of sovereignty with regard to decision-making

Benefit for regulators; sharing of workload, but independent decisions

«Foundation», Equivalence of requirements

Ward M: Reliance in the Context of Good Regulatory Practices.2017

Regulatory Harmonization and Collaboration

- Member of PIC/S
- Observer status on ICH and EDQM
- Member of IGDRP group
- Cooperation with other regulatory authorities (HSA, FDA, EMA, TGA, Swissmedic, MHRA)
- SADC – MRH, Zazibona
- AMRH
- Member of AVAREF
- Member of WHO PQ
- Member of WHO Programme for International Drug Monitoring - Established 1968 based on thalidomide tragedy, establish worldwide pharmacovigilance standards and systems

Envisaged Changes

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Backlog Project

- Delays in registration of applications attributable to:
  - Increasing number of generic applications
  - Large number of post-registration variations/amendments
  - Historical procedures for fast-track
  - Availability of skilled reviewers
  - Limited abbreviated procedures and application of reliance models
  - IT infrastructure
  - Absence of project management and logistical support
- Current process ineffectual in providing timely access to, especially generic medicines.

Backlog Project

- Understanding the Backlog
  - Proposed definition: All applications received up to 31 January 2018
- Local Benefit-Risk considerations
- Unmet medical need
- Fast-track review using different approaches and models (International best practice)
- Registration status elsewhere
- Status:
    - In-process – update
    - To be allocated
- Stratification of applications:
    - Generic applications
      - Duplicates/multiples
      - Different strengths
      - Older vs newer molecules
    - NCEs
      - Clones
      - Different strengths

Thanks and Questions?