# Are we there yet? Destination SAHPRA

**18 August 2017**

Bytes Conference Centre (Midrand)

Joey Gouws

# Overview

- Introduction
- History of MCC Review
- Status of SAHPRA
- SAHPRA versus MCC
- Closure

# Medicines Control Council (MCC)

The Medicines and Related Substances Act, 1965

- Enacted 1965
- Provides for certain powers:
  - Minister of Health
  - Director General: Health
  - Medicines Control Council (MCC)
- MCC mandate:
  - Registration of medicines : Safety, quality and efficacy
  - Licensing of Manufacturers, Wholesalers, Importers
  - Authorization conduct of clinical trials

# History of MCC Review

## Historical

- 1998: Review of medicine regulatory system – Prof Graham Dukes
- 1998: Operational and Financial review - KPMG
- 1998:Transitional Task Team – Prof Helen Rees
- 1999: SAMDRA Act and its repeal
- 2002: Medical Technical Task – Ms Precious Matsoso (WHO)
- 2006: Parliament directed review – Prof Green-Thomson
- 2008: Act 72 of 2008
- 2012: Business case: Nicholas Crisp
- 2014: Transitional Task Team – Prof Helen Rees
- 2015: Act 14 of 2015

**Reviews support the transition to a new business model to allow for:**

- **Service delivery**
- **Communication**
- **Operational processes**

# SAHPRA

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
- Act 14 of 2015: Transitional arrangements : MCC to SAHPRA
  - 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

# SAHPRA ….cont

SAHPRA is proposed to:

- 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

SAHPRA will be responsible for:

- monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, clinical trials and medical devices and related matters in the public interest.

# Status of SAHPRA ….cont

- Act 72/2008 enacted: 1 June 2017
  - This enacted also Act 14 of 2015
- General Regulations prepared on SAHPRA Act
  - Regulations for publication: 11 August 2017
- Minister: calls for nominations for the Board to be appointed
  - Advertisement for Board members – deadline 30 June 2017
  - Board consists of 10-15 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
  - Nominations received: under consideration

# Status of SAHPRA ….cont

- Minister: calls for 1st meeting of the Board
  - Orientation of the Board
  - MCC will cease to exist with 1st Board meeting
  - Board appoint CEO
  - Board appointment committees to assist with work of the Board
  - CEO appoint committees to assist with work of Authority
  - Authority works through the Board
- DOH staff to transfer to SAHPRA
  - Section 197 transfer
  - Staff component: 207

# Status of SAHPRA ….cont

Business case developed for SAHPRA by Project Team

- Statutory and Legal
- Media
- Human Resources – Organisational Development
- Human Resources – Policies
- Job descriptions
- CEO performance agreement
- Finance
- Information Technology
- Implementation plan

# SAHPRA Business model

Requirements:

- effective, efficient and transparent systems of financial and risk management and internal control
- a system of internal audit under the control and direction of an audit committee complying with and operating in accordance with regulations and instructions prescribed in the PFMA
- an appropriate procurement and provisioning system which is fair, equitable, transparent, competitive and cost-effective

# SAHPRA

*S2(1) The South African Health Products Regulatory Authority is hereby established as an organ of state within the public administration but outside the public service.*

## BOARD

***S2(5) The Authority acts through its Board***
*(as it pertains to business and not execution of responsibilities of authority)*

S2C – Composition, S2D, E, F – Appointment, Chair, Disqualification

S2G – Meetings of the Board
*(1) The **meetings of the Board and the conduct of business at meetings** must be determined **by the rules of the Board.***

## COMMITTEES (OF BOARD)

S2H – Committees of Board
*The Board may appoint one or more committees from among its members to **assist** it with **the performance of its functions.***

## CEO

S3(1) Appointed by the Board (after consultation with Minister)

*S3(4) (e) is responsible for the **general administration** of the Authority and for the **carrying out of any functions assigned to the Authority** by this Act and the Minister;*

## STAFF

*S3(5) The Chief Executive Officer shall appoint suitably qualified staff and may contract other suitably qualified persons to assist the Authority in carrying out its functions.*

*S34A(3) The Chief Executive Officer may, in writing, authorise any staff member of the Authority to exercise or perform in general or in a particular case or in cases of a particular nature, **any power, duty or function conferred or imposed on the Chief Executive Officer in terms of this Act.***

## COMMITTEES (OF CEO)

*(9) The Chief Executive Officer shall, in consultation with the Board, appoint committees, as he or she may deem necessary, to investigate and report to the Authority **on any matter within its purview in terms of this Act**.*

**STATUS REPORTED**

## REGISTRATION OF MEDICINES AND MEDICAL DEVICES

***S15(3), (4), (5)***

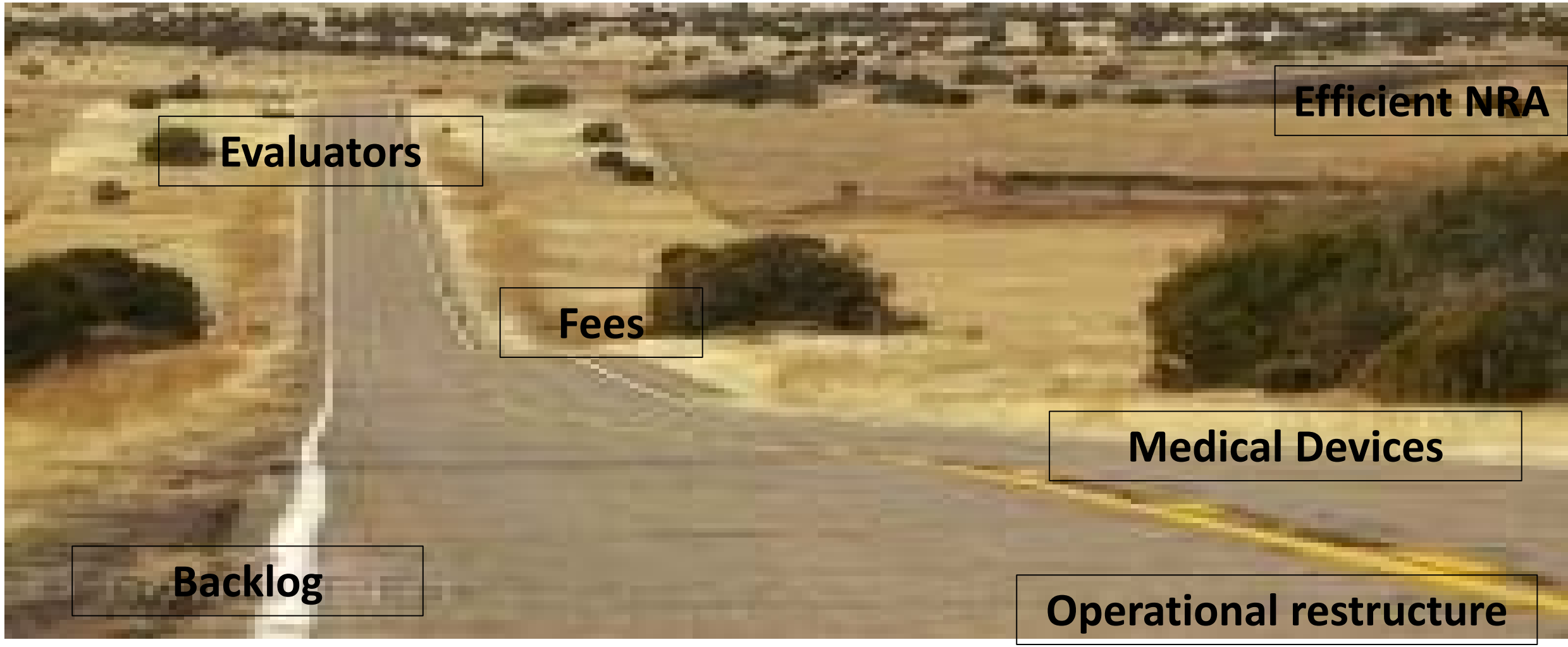
# SAHPRA versus MCC

- Business model based on business principles
- Staff employment: reporting lines – SAHPRA
- Performance driven (In-house and External staff)
- Registration and Authorizations issued by Authority
- Transparency
- Retain revenue
- MoU with other Regulators
  - Allow for acceptance of international evaluation reports

# SAHPRA vs. Existing Model
# The fundamental differences

| SAHPRA | Existing Model |
|---|---|
| Medicines, Devices (incl. IVD's and Radiation Control), CAMS | Medicines, (Radiation Control part of NDOH) |
| System driven | Paper driven |
| Service delivery with defined timelines | Service delivery with backlogs |
| Fully resourced | Under resourced |
| Increased employed and contracted evaluators (80/20) | Limited employed evaluators (20/80) |
| Public entity – Fully accountable | Part of the Department of Health |
| Transparent industry relations | Stretched industry relations |
| Increased and retained fee income | No fee retention |
| Agency format | Traditional government format |
| Proactive performance measurement (managed service levels) | Reactive |
| Accrual based accounting | Cash based accounting |

# Closure


Evaluators
Efficient NRA
Fees
Medical Devices
Backlog
Operational restructure


Thank you !
www.mccza.com