Industry Transition to SAHPRA

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Bytes Conference Centre (Midrand)

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Overview

- History of MCC Review
- Legislation: Establishment of SAHPRA
- SAHPRA model
- What does this mean for Industry
- Closure

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:

- **Greater service delivery**
- **Greater communication**
- **Improved operational processes**

SAHPRA

The Medicines and Related Substances Act, 2008 as amended (Act 72 of 2008)

- Established SAHPRA as a Public Entity
- Extended the mandate to include Medical Devices

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

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.***
[Remuneration. Audit. Executive]

STATUS REPORTED

REGISTRATION OF MEDICINES AND MEDICAL DEVICES

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

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**.*

Vision
SAHPRA vs. MCC 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

What does this mean for Industry

Requirement 3A Public Entity	Industry Implication
Entity is listed as a **National Public Entity (3A)** Extension of Department of Health Nature and level of autonomy (PFMA)	
Board established with business model based on **business principles** with accounting authority	
Finance Substantially funded from National Revenue Accrual based accounting Retain revenue	Fees increase Invoices received and honoured
Authority **accountable** to Parliament through Minister as Executive authority Financial statement Financial reports Functions of Authority	Greater transparency Industry to follow parliament process and attend

What does this mean for Industry ....cont

Requirement Business model	Industry Implication
Business model based on business principles and **forces that shape business** • Government & Regulations • Globalisation • New Technologies (IT) • Change in Society expectations • Increased Ethical Values	• Ensure SAHPRA compliance with Regulations • Understand International best practices • IT Implementation: eCTD, EDMS • Public Health and need for priority medicines • Monitor ethical values and conflict of Interest of SAHPRA – Evaluators, Inspectors

What does this mean for Industry ....cont

Requirement Business model	Industry Implication
Business and **organizational behavour**	

• Greater service delivery
  ○ Performance agreements with Evaluators
  ○ Output and Timelines
	• Comply with SAHPRA requested response timelines

• Communication
  ○ Website design
  ○ Information and Guidelines
  ○ Open door policy
	• Monitor website for latest information, communication to Industry
	• Discussions: pre-submission / resolution clarification

• Improved Operational processes ○ Reengineering registration process	• Electronic submissions

What does this mean for Industry....cont

Requirement Mandate: Medical Device and IVD	Industry Implication
Legislative requirements: • Licensing	Understand requirements, develop QMS and submit application
• Product review	Not yet applicable, prepare Technical dossier
• Vigilance reporting	Understand reporting and submit Adverse reports
• Advertising	Understand and follow requirements

SAHPRA ….cont

SAHPRA is proposed to:

- establish **cooperation and information** sharing with other NRAs to support implementation of best practices and timely approval of products

What does this mean for Industry....cont

Requirement NRA: Cooperation and Information sharing
Does not yet exists and thus does not allow for reciprocity or reliance by could use in innovative way • MoU with other NRA's   ○ No real effect on Industry
• Harmonised Standards / Best practices
• Reliance

What does this mean for Industry....cont

Requirement Support Best Practices	Industry Implication
PIC/S [Pharmaceutical Inspection Cooperation Scheme] **MCC Member status**	Understand and implement GMP / GCP requirements
ICH [International Council for Harmonisation of Technical Requirements for Pharmaceutical Products] **MCC observer status**	Follow requirements and reflect in CTD
WHO: Pre-Q **MCC signature**	Understand and submit dossier according
SADC: Zazibona **MCC participation**	Understand and submit dossier according
VICH [International Council for Harmonisation of Technical Requirements for Veterinary Products] **MCC observer status**	Follow requirements and reflect in CTD
AVAREF: Clinical trials **MCC participation**	Understand WHO GCP and protocol requirements
IMDRF [International Medical Devices Regulatory Forum] & GMDN coding **MCC observer**	Understand and implement Guidelines & Coding

What does this mean for Industry....cont

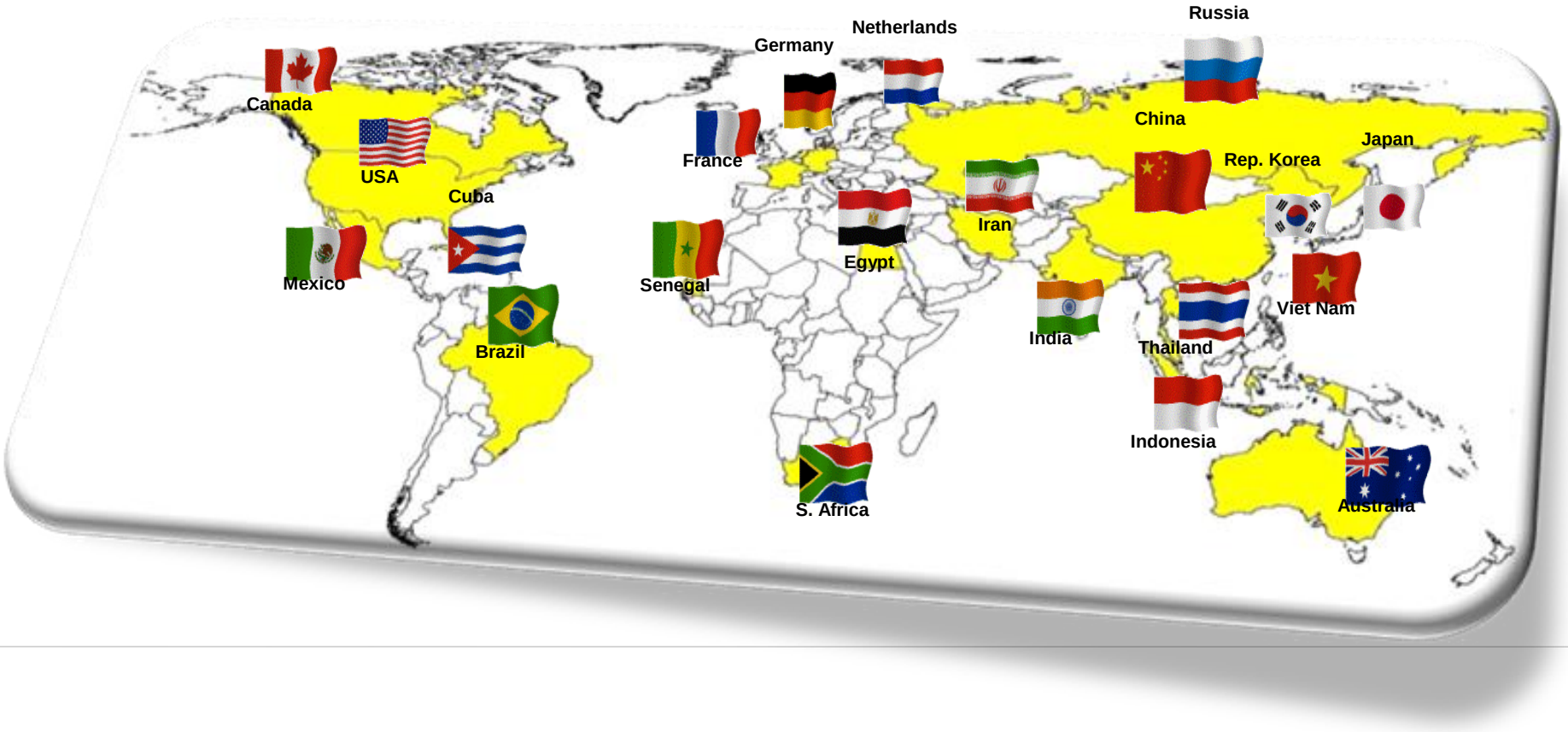
Requirement Support Best Practices	Industry Implication
WHO: Vigiflow Pharmacovigilance monitoring **MCC obtained programme**	Submit ADR as per MCC Guidelines
SAHPRA Intelligence • CAMS: NRA's that SAHPRA aligns with ○ Therapeutic levels	Understand and submit dossier according
• EMEA Quality defect reporting **MCC member as WHO member country**	Report imported product Quality defect to MCC
• Access to medicines: Scheduling status (down scheduling / up scheduling)	Report changes on access to SAHPRA • Request for down scheduling / up scheduling

What does this mean for Industry....cont

Requirement Reliance	Industry Implication
Medical Devices / IVDs Manufacturing Site QMS compliance Assessment of Technical dossier	
• MoU between MCC and SANAS ○ Development of ISO Standards	Understand and implement ISO Standards
○ Accreditation of Notified bodies	Understand and implement ISO Standards
Medicines Manufacturing Site GMP compliance Assessment of dossier	Submit Inspection report from NRA's
• NRAs that SAHPRA aligns with	Submit un- redacted copies of evaluation reports Evidence that medicine is identical: dosage form, strength, formulation, manufacturing site

Closure

Globally NRA's in collaboration with Industry strive for better regulation to allow for the development and marketing of safe and effective products and ensure prompt and effective patient protection.




Thank you !
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