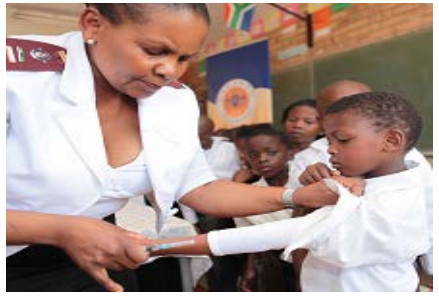

Medicines Control Council & update on SA Health Products Regulatory Authority

South African Pharmaceutical Regulatory Affairs Association (SAPRAA)

08 April 2016

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Outline

- Introduction
- Policy & Legislative Framework
- MCC mandate & obligations
- Effective medicine regulation
- How the MCC works
- Objectives of Amendment Act 72 of 2008
- Objectives of Amendment Act 14 of 2015
- Funding implications
- Remedial measures already undertaken
- Conclusion

Introduction

- The role of a national medicine regulatory authority (NRA) is to guarantee the quality, safety and efficacy of medicines [NHA]
- Countries are aware of this the reason why various Authority are in place:
  - Europe has got EMEA (European Medicines Agency)
  - US has got FDA (Federal Drug Administration
  - Switzerland has got SWISSMEDIC
  - Zimbabwe has got MCAZ (Medicines Control Agency of Zimbabwe
  - Australia has got TGA (Therapeutic Goods Administration)
  - South Africa has MCC (Medicines Control Council)

Effective Medicine Regulation: WHO 1999

In accordance with the WHO, the elements of an effective regulator:

- Decisions should be based on **scientific evidence** and facts
- Practicable enforcement capacity
- Accountability and public interest/public good
- Safeguard against conflict of interest
- Limit **discretionary** powers
- Good regulatory practices and standards
- Independence from **public, commercial** and **political pressure**

Policy & Legislative Framework

- The National Drug Policy, requires safe, quality and effective medicines to be available to the public.
- Medicines and Related Substances Act of 1965 therefore provide for:
  - The registration of medicines and related substances for human and animal use
  - The establishment of the MCC
  - The control of medicines and scheduled substances

MCC Mandate

- Registration of human and animal medicines and related substances based on safety, efficacy and quality
- Approval and monitoring of clinical trials
- On going monitoring of safety
- Post marketing surveillance
- Licensing manufacturers, wholesalers and distributors
- Provision of information as per PAIA.

Obligations

- Public safety
- Public protection
- Transparency
- Accountability
- Timely action on safety and quality
- Responsiveness
- Continuous risk assessment – minimization of harm and maximization of benefit

BACKGROUND

HOW THE MEDICINES CONTROL COUNCIL WORKS

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20 YEARS OF FREEDOM
south africa 1994 - 2014

HOW THE MCC WORKS

- The Medicines Control Council (MCC) comprises twenty-four members appointed by the Minister for a 5-year term of office renewable once.
- Technical competencies of members are defined in law

- Evaluators drawn from:
  - Academia, Research Institutions, Practice settings,
  - Few in-house staff

How the MCC works….cont

- Ten Expert (Peer Review) committees appointed by the MCC after consultation with the Minister.
- Committees meet every 4-6 weeks.
- Sub-committee Working groups appointed when necessary.
- Adherence to Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and Good Distribution Practice (GDP) monitored by inspectors employed by NDoH and overseen by the MCC.

How the MCC works....cont

- MCC meets every 6 weeks for decision making
- Executive Committee of the MCC meets when necessary
- Registrar keeps register of:
  - Registered products
  - Licensed manufacturers, distributors, laboratories
  - Information posted on MCC website

Medicines Control Council & Expert Committees

- **Medicines Control Council Chairperson**
  - **Medicines Control Council** Vice Chairperson
  - **Registrar of Medicines**
  - **Pharmaceutical and Analytical Committee**
    - **Biological Medicines**
    - **Names and Scheduling**
    - **Veterinary Clinical**
    - **Legal Committee**
  - **Complementary Medicines**
    - **African Traditional Medicines**
  - **Clinical Trials Committee**
    - **Clinical Committee**
    - **Pharmacovigilance Committee**

How the MCC works ….cont

Staff component of current Medicines Control Council (MCC)

- Members: 24
- Evaluators (part time) in Committees: 110

Staff component of in-house DoH staff

- Technical & Administrative: 180

Business model of MCC dated and no longer effective

Workload of MCC increased:

- 1200-1600 applications per annum
- Complementary medicines (120 000 on record)
- Clinical trials 320 per annum

Establishment of a new Medicines Regulatory Authority

Objectives of Amendment Act ACT 72 OF 2008

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Establishment of a new Regulatory Authority

Decision 2007: establish SAHPRA (South African Health Products Regulatory Authority)

- organ of State within the public administration
- outside the public service
- regulate medicines and medical devices

Amendment the Medicines and Related Substances Act, 1965 (principal Act)

- Medicines Amendment Act, 2008 (Act 72 of 2008) ("amendment Act")
- signed into law by President Kgalema Motlanthe in 2009
- not implemented : corrections and extended mandate.

Why the amendment

- **2003: Noble pro-access policies implemented**
  - unforeseen consequences – an exponential increase in the number of medicine applications mainly generics
  - Result: inordinately long evaluation time-lines

- **MCC structure conceived in 1965**
  - relies heavily on external experts who have primary jobs elsewhere
  - no longer appropriate – lends itself to inefficiency

Why the amendment ....cont

- Scientific advances and complexity of innovative products
- Insufficient similarity between internal NDoH staff that act as secretariat to the MCC
- Strengthening in-house capacity
- Operationalising and strengthening SAHPRA as a juristic person

Why the amendment ….cont

- Retention of revenue raised through fees to enable beefing up capacity and improving efficiency
- More efficient use of available resources e.g. GMP, GCP, GLP and GDP inspectors
- More efficient use of Law Enforcement officers to cover all areas of regulation
- Better management of areas of overlap e.g. combination devices, medicines

Amendment Act 72 Objectives

- Expansion of functions to include regulation of medical devices and *in vitro* diagnostics, Complementary and Alternative medicines and blood derived products
- Flexibility of remuneration structure in order to attract and retain scarce skills in consultation with the Minister of the Public Service Administration and the Minister of Finance
- Operation in accordance with Good Business Principles

Amendment Act 72 : Principles

- Good governance
- Project management of activities and registration processes
- Accountability and responsibility
- Strengthening transparency and communication
- Continued professional development
- Good review practices
- International regulatory co-operation through co-operation agreements with selected foreign regulatory authorities

Relationships

- Relationships with other government departments e.g. Agriculture Forestry and Fisheries, Trade & Industry, Science & Technology on matters of common interest
- Relationships with academic institutions, professional councils and regulators of other products other than health related
- Relationships with law enforcement agencies, local and international

Status of Amendment Act 72 of 2008

Though amendment Act 72 of 2008 was approved by Cabinet and Parliament and signed by the President, it has not yet been implemented.

OBJECTIVES & REASONS FOR CURRENT AMENDMENT, ACT 14 of 2015

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Update on the Legislative Process

- The Amendment Bill 6B has gone through a full cycle of the legislative process where it has been deliberated and shaped by inputs from various parliamentary committees.
- Provincial Briefings and public hearings were undertaken in all nine provinces as required by law on a matter that may possibly affect provinces.
- Public inputs on the Bill and SAHPRA have been incorporated into the Amendment Bill as assented.
- Both the houses (NA and NCOP) of Parliament were satisfied that there was adequate consultation on the Amendment Bill.
- The President has assented to the Amendment Bill and it awaits proclamation for it to take effect.

Why the current amendment

- To strengthen the governance of the proposed South African Health Products Regulatory Authority (SAHPRA), as a Schedule 3A Public Entity
- To provide for the establishment of a Board
- To provide for the functioning of SAHPRA under the Board
- To define functions & responsibilities of the Board
- To include provisions that enable the recognition of work done by selected regulators in order to reduce duplication of effort in the statute

Why the current amendment …cont

- To strengthen transitional measures to facilitate migration of MCC to SAHPRA
- To provide for consequential amendments that replace “MCC” with SAHPRA
- To provide for consequential amendments that replace “MCC” with the Board e.g. in relation to meetings, appointment of chairperson and vice chairperson of the Board, disqualification of members, quorum
- To replace the word “products” with medicines and scheduled substances to ensure precision and technical correctness

Why the current amendment …cont

- To explicitly define the functions of SAHPRA within the statute
- To affirm the intention to establish SAHPRA outside the public service but remain within the public administration
- To provide for reduction of duplication of effort through recognising work done by other regulators and *vice versa* by including an enabling clause in the statute

Functions of the Board

- Determine policy
- Draw up plans on functions, powers and duties
- Review and approve audited financial statements
- Evaluate the performance of SAHPRA
- Prepare annual reports on finances and performance
- Submit annual reports to the Minister for tabling in Parliament
- Appoint one or more committees from amongst its members to assist with the performance of its functions
- Appoint a CEO in consultation with Minister
  - The CEO - an *ex officio* member of the Board

Functions of Chief Executive Officer

- Appoint committees in consultation with the Board
  - to investigate and report to the Board on any matter within the purview of the Act
- Keep and publish Registers of
  - regulated medicines
  - medical devices
  - *In-vitro* diagnostics

Transitional arrangements

For operational reasons various transitional provisions are provided for to allow for:

- the commencement date of the new Authority,
- the ceasing of the work of the MCC
- the transfer and designation of the employees of the NDoH to SAHPRA and processes related there to
- the registration status of any medicine or medical device
- ownership and control of moveable properties
- status of the fees/ revenue collected by the MCC.

South African Health Products Regulatory Authority (SAHPRA)

MINISTER

SAHPRA – Section 3A public entity

BOARD

CEO

Risk Audit Committee (PFMA)

Administrative

- **Chief Financial Officer**
- **Executive Manager: Corporate Services**

Technical Support (Executive Manager)

- **Authorization Management**
- **Inspectorate & Regulatory Compliance**

Regulatory

- **Medicines**
- **Medical Devices and Diagnostics (Inc IVDs & Radiation Control)**
- **Complementary and Alternative (CAMS) Medicines**

Funding implications

- For effective functioning:
  - SAHPRA will be partly reliant on Government funding through public money, by means of a transfer from the Revenue Fund
  - partly from funds (fees) raised for services rendered within its regulatory ambit.

REMEDIAL MEASURES ALREADY BEING IMPLEMENTED

Regulation of poorly & unregulated commodities

CAMS:

- Regulations for control of Complementary and Alternative medicines published in November 2013
  - being implemented in a phased approach.
  - Further work to refine this area is ongoing

Medical Devices and *in vitro* Diagnostics:

- Regulations published for comment with closing date August 2015.
- Regulations to be published for implementation 2016

Capacity building

- The quantum of full time equivalents of staff is estimated at about 200 at entry
- Training of 25 science graduates (Masters and PhD graduates) on regulatory assessment methods completed June 2015
  - 8 internal staff
- Medium-term: establishment of a regulatory science institute
  - implementation model and option appraisal completed
  - Business plan under development

Relationships

- MOU's already signed with selected regulatory authority
  - SwissMedic (Switzerland)
  - MHRA (United Kingdom)

Status of SAHPRA [Where We are]

- Amendment Act 72 of 2008 was approved by Cabinet & Parliament and signed by the President, it has not yet been implemented.
- Amendment Act 14 of 2015 was approved by Cabinet & Parliament and signed by the President, it has not yet been implemented.
- MCC preparing for transition to SAHPRA:
  - Discussions with National Treasury
  - Appointment of critical staff
  - New premises

Conclusion

- The intention is that SAHPRA will:
  - address challenges of access to quality, safe and affordable medicines and medical devices / IVDs
  - Improve efficiencies in the current system
  - fast-tracking the registration of priority public products
  - make essential medicines and products more readily available
  - potentially reduce prices through increased competition and licensing of generic products.

Conclusion …cont

SAHPRA is proposed to:

- have full-time in-house capacity to support product review & approval & 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:

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

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Conclusion …cont

It is evident that globally, NRAs are developing rapidly and South Africa needs to follow that direction. The area of individual NRAs is declining and networks of regulators are getting more important. South Africa also needs to rely more on harmonized approaches with other agencies and its increase added value activities.

I thank you

On behalf of the Registrar: MCC

Adv Ezra Letsoalo

Legal Technical Officer

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