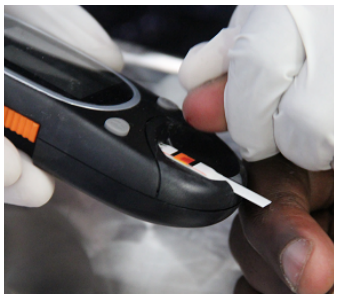

Portfolio Committee on Health

BRIEFING ON THE MEDICINES AND RELATED SUBSTANCES AMENDMENT BILL

Date: 3 September 2014

health
Department:
Health
REPUBLIC OF SOUTH AFRICA

20 YEARS OF FREEDOM

Outline

- Policy & Legislative Framework
- MCC mandate & functions & obligations
- Pillars of effective regulation
- How the MCC works
- Objectives of Amendment Act 72
- Why the current amendment
- Funding implications
- Remedial measures already undertaken

Policy & Legislative Framework

- National Drug Policy
- Medicines and Related Substances Act of 1965 to 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
- Monitoring of safety
- Post marketing surveillance
- Licensing manufacturers, wholesalers and distributors
- Provision of information

Obligations

- Public safety
- Public protection
- Transparency
- Accountability
- Timely action on safety and quality
- Responsiveness

•Continuous risk assessment – minimization of harm and maximization of benefit

ELEMENTS OF EFFECTIVE REGULATION

- 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**

Barriers to Effective Regulation WHO 1999

- Absence of policy, weak legislation and regulation
- Insufficient human resources
- Lack of financing
- Corruption
- Absence of transparent procedures

BACKGROUND (1)

HOW THE MEDICINES CONTROL COUNCIL WORKS

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, very few in-house
- 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 MCC WORKS (2)

- MCC meetings every 6 weeks for decision making
- Executive committee of the MCC when necessary
- Registrar keeps register of:
  - Registered products
  - Licensed manufacturers, distributors, laboratories and any other pertinent matters
  - 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 Committee

Names and Scheduling Committee

Veterinary Clinical Committee

Legal Committee

Complementary Medicines Committee

African Traditional Medicines

Clinical Trials Committee

Clinical Committee

Pharmacovigilance Committee

Biotherapeutics subcommittee

Interaction between MCC and NDoH

Minister of Health

MCC

Registrar

Deputy Registrars

MCC: no staff

Cluster MRA

MRA Staff

Inspectorate

National DOH

NDOH
-Issue permits
-Issue licences

Evaluators Expert Committee

Outsourced Services

National Treasury

Minister of Finance

BACKGROUND (2)

OBJECTIVES OF AMENDMENT ACT 72 OF 2008

Why the amendment (1)

- Noble pro-access policies implemented in 2003 had an unforeseen consequence – an exponential increase in the number of applications for registration particularly generics
- This has resulted in inordinately long evaluation time-lines
- The structure of the MCC conceived in 1965 relies heavily on external experts who have primary jobs elsewhere is no longer appropriate – lends itself to inefficiency

Why the amendment (2)

- Accommodation of poorly regulated and unregulated products e.g.
  - complementary and alternative medicines
  - African Traditional Medicines
  - medical devices and *in vitro diagnostics*
  - foodstuffs
  - blood products
  - cosmetics
- Cabinet resolved in January 2006 that the challenges of the MCC be addressed

Why the amendment (3)

- Scientific advances and complexity of innovative products
- Insufficient congruence between internal NDoH staff that act as secretariat to the MCC
- Rationalisation of different regulatory functions operating within the health product arena and overseen by the NDoH
- Strengthening in-house capacity
- Operationalising and strengthening SAHPRA as a juristic person

Why the amendment (4)

- 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, food control and medicines

Amendment Act 72 Objectives (1)

- The establishment of a full - time South African Health Products Regulatory Authority (SAHPRA) as a Government Agency accountable to the Minister
- Juristic person
- Appointment of a full time Chief Executive Officer as accounting officer by the Minister
- The establishment of an Advisory committee appointed by the Minister to oversee the functioning of the Authority
- Streamlining the Appeal process

Amendment Act 72 Objectives (2)

- Expansion of functions to include regulation of Foodstuffs in relation to food safety aspects, medical devices and *in vitro* diagnostics, Complementary and Alternative medicines, African Traditional medicines, cosmetics and blood derived products
- Retention of revenue raised through fees
- 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
- 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

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

OBJECTIVES & REASONS FOR CURRENT AMENDMENT

Why the current amendment (1)

- To strengthen 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 instead of an Advisory Committee
- To provide for the functioning of the SAHPRA under the control of the Board
- To define functions and 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 (2)

- To strengthen transitional measures in order to facilitate the migration of the MCC to SAHPRA
- To provide for consequential amendments that replace the MCC with SAHPRA where applicable
- To provide for consequential amendments that replace the 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 (3)

- To more explicitly define the functions of SAHPRA within the statute
- To more explicitly provide for the regulation of biological medicines inclusive of plasma-derived and animal products, biotechnology-derived medicines as well as products developed through human gene therapy
- To strengthen sections relating to the regulation of complementary & alternative medicines

Why the current amendment (4)

- To affirm that though the intention is to establish SAHPRA outside the public service, it should still be 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 the policy
- Draw up plans in relation to the 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 Chief Executive Officer, in consultation with the Minister
- The Chief executive Officer will be an *ex officio* member of the Board

Functions of the 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 on the website registers of regulated medicines, Scheduled substances, medical devices or *in vitro diagnostics.*
  - The latter functions were assigned to the Registrar in Act 101 of 1965 the Medicines and Related Substances Act

Transitional measures

- Appointment of transitional team to prepare for the implementation of SAHPRA under consideration
- Arrangements with NDoH on support with corporate functions and gradual phasing out to SAHPRA to be implemented
- Arrangements with NDoH on transfer of staff and assets to be implemented

REMEDIAL MEASURES ALREADY BEING IMPLEMENTED

Regulation of poorly regulated and unregulated commodities

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

- Draft Regulations for the regulation of Medical Devices and *in vitro* diagnostics were published for comment. The commentary period closed in August 2014

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), eight of whom are internal staff will commence in September in regulatory assessment methods
- Medium-term the establishment of a regulatory science institute is being explored. An implementation model and option appraisal have already been done

Relationships

- Work to establish MOUs with one selected regulatory authority quite advanced
- A technical framework has been agreed-to
- MOU expected to be finalised by end of October
- Working relationships on food control strengthened with relevant government departments through joint projects