REVIEW OF MEDICINES CONTROL COUNCIL AND RECOMMENDATIONS ON THE NEW REGULATORY AUTHORITY

Presentation to the Health Portfolio Committee
Tuesday, 29th July 2008

WHY THE REVIEW (1)

- Complaints about the Efficiency and Outputs of the Medicines Control Council (MCC)and the Medicines Regulatory Affairs (MRA)(Chief Directorate in the Department)
- Disjointedness of the MCC and MRA as an Operational System
- Global Trends for the review of Regulatory Authorities every five years
- Current MCC conceived in 1965 and never reviewed

2

WHY THE REVIEW (1)

- Scientific Advances in and the increasing complexity of health products
- Lack of and/or weak regulation of some health products
- Rationalization of different regulatory authorities operating in health product arena. Have one Regulatory Authority to consider the certification of all Health Products.
- Clarification of the registration process

3

PROPOSALS FOR A NEW REGULATORY AUTHORITY FOR HEALTH PRODUCTS FOR SOUTH AFRICA FROM THE MINISTERIAL TASK TEAM REPORT

4

STRUCTURE (1)

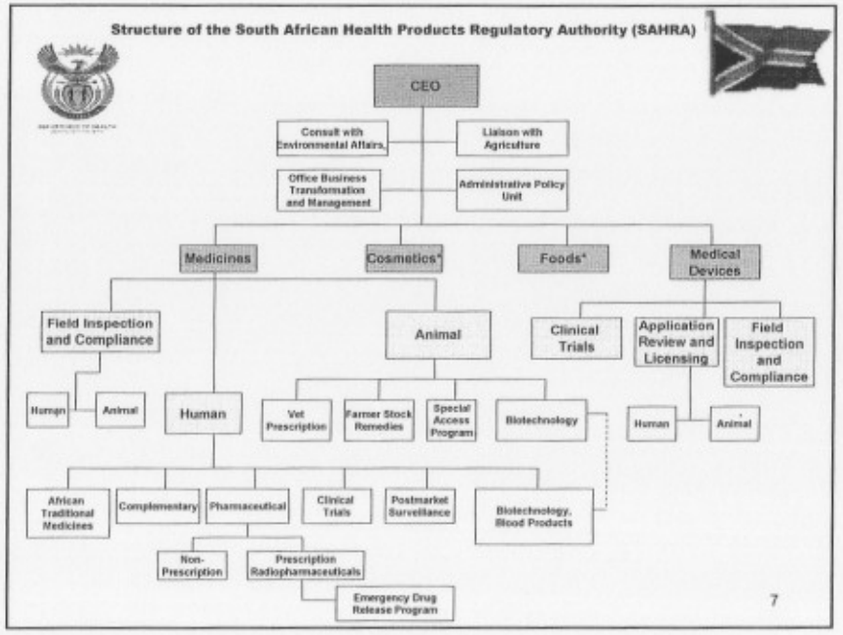
- Establishment of the South African Health Products Regulatory Authority (SAHPRA)
- SAHPRA should be an Agency,
- Accountable to the Ministry of Health
- Juristic Person
- Retain revenue from fees and be 50% cost recovery.
- Have a flexible remuneration structure so as to be able to recruit and retain scarce skills. This will ensure human resource adequacy.
- Business principles and ensure good governance.
- Headed by a full time CEO who is the accounting officer subject to the PFMA and the other legal prescripts.

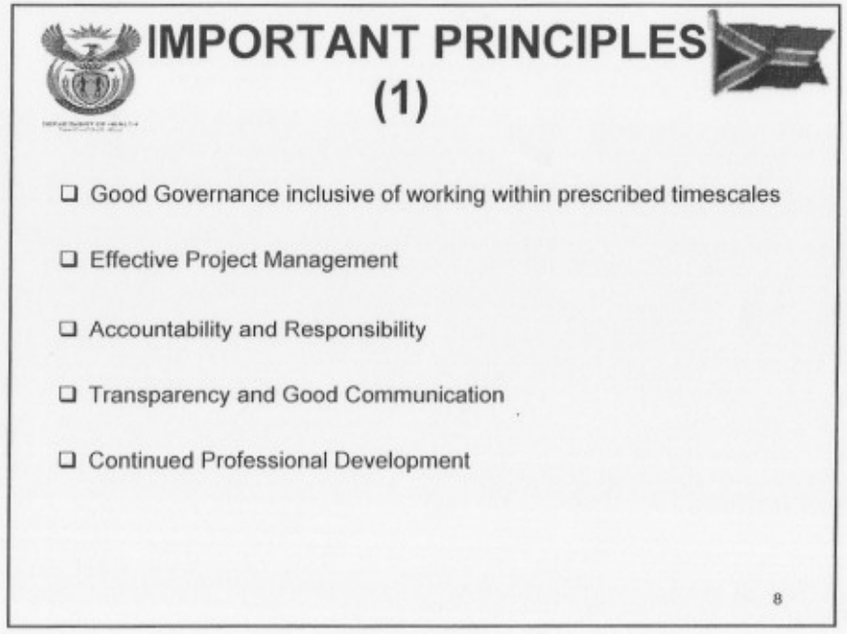
5

STRUCTURE (2)

- SAHPRA must be an Overarching Regulatory Authority for Health Products for South Africa to include Medicines, Medical devices, foods and cosmetics with medicinal claims and/or medicine content (All health products for humans and animals)
- SAHPRA must also regulate all animal health products with medicinal claims or medical contents which is the global trend of regulatory authorities of health products.

6


Structure of the South African Health Products Regulatory Authority (SAHRA)
CEO
Consult with Environmental Affairs
Liaison with Agriculture
Office Business Transformation and Management
Administrative Policy Unit
Medicines
Cosmetics*
Foods*
Medical Devices
Field Inspection and Compliance
Animal
Clinical Trials
Application Review and Licensing
Field Inspection and Compliance
Human
Animal
Human
Vet Prescription
Farmer Stock Remedies
Special Access Program
Biotechnology
Human
Animal
African Traditional Medicines
Complementary
Pharmaceutical
Clinical Trials
Postmarket Surveillance
Biotechnology, Blood Products
Non-Prescription
Prescription Radiopharmaceuticals
Emergency Drug Release Program
7


IMPORTANT PRINCIPLES (1)
Good Governance inclusive of working within prescribed timescales
Effective Project Management
Accountability and Responsibility
Transparency and Good Communication
Continued Professional Development
8

IMPORTANT PRINCIPLES (2)

- ❑ Monitoring and Evaluation
- ❑ Enhanced review capacity and good review practices
- ❑ Change Management
- ❑ International Regulatory Co-operation
- ❑ Consultation with Experts/Expert Panels where indicated
- ❑ Regular Review

9

FUNCTIONS (1)

- ❑ Evaluate all medicines, medical devices and other health products with medicines or medical content for efficacy, safety and quality
- ❑ Evaluate all blood derived products used for medicinal purposes
- ❑ Certify all the above for efficacy, safety and quality
- ❑ Authorise the conduct of clinical trials, both human and animal
- ❑ Conduct post-marketing surveillance and Pharmacovigilance

10

FUNCTIONS (2)

- Keep a register of all certified and registered products
- Conduct inspections as and when necessary (Good Manufacturing Practices, Good Clinical Practices, Good Distribution Practices, Good Marketing Practices)
- License manufacturers, wholesalers and distributors

11

RELATIONSHIPS (1)

- Concurrence of the Minister of Agriculture on the registration of veterinary medicines and other animal health products and other matters of common interest e.g. Genetically Modified Organisms
- Co-operation and agreements with other selected foreign regulatory authorities
- Agency function
- Relationship with other regulatory authorities of products other than health products, professional councils, academic institutions, etc.

12

RELATIONSHIPS (2)

- Relationship with law enforcement agencies local and foreign
- Relationship with the Patents Office
- Relationship with other government departments eg Environmental Affairs, Science and Technology, Trade and Industry

13

EFFICIENCY GAINS

- Enhanced capacity // physical, financial, human and systems
- Good governance
  - Retention of revenue, 50% cost recovery and adequate capex and opex
  - Recruitment and retention of staff
  - Improvement of systems
  - Timeous access to new technologies
- Transparency and accountability
- Improved time scales. Work within prescribed timescales.

14

OTHER RECOMMENDATIONS

- Enforcement of a Code of Good Marketing Practice
- The need to explore the need of a safe product body

15

DRAFT LEGISLATION ON SAHPRA (1)

PROVISIONS OF THE BILL

- Establishment of a full time South African Health Products Regulatory Authority ("the Authority") whose mandate will be evaluate the safety, quality and efficacy of medicines and other health products and certify them accordingly.
- Once medicines have been certified as being safe, of good quality and efficacious, the application is then referred to the Minister who shall register such medicines if it is in the public interest to register such medicines.
- The bill also provides for the authority to also look at the safety of foodstuffs and cosmetics which have medicinal components in them or that make medicinal claims.

16

DRAFT LEGISLATION ON SAHPRA (2)

Specifically, the Bill provides for the following:

- the appointment by the Minister of a Chief Executive Officer of the Authority , reporting & responsible to the MOH, who shall appoint staff for the Authority and who shall be responsible for the general administration of the Authority.
- the certification of medicines; medical devices; foodstuffs and cosmetics by the Authority in relation to their safety, quality and efficacy.
- registration of medicines; medical devices; foodstuffs and cosmetics by the Minister if it is in the public interest to do so.

17

DRAFT LEGISLATION ON SAHPRA (3)

- Registration of veterinary medicines and other animal health products shall be done with the concurrence of the Minister of Agriculture
- appeals against the decisions of the Authority, that such appeals shall be heard by an appeal committee convened by the Chief Executive Officer and such appeal committee shall also include persons nominated by the appellant. Appeals against the decisions of the Minister are not provided for in the Bill which means that persons aggrieved by the decisions of the Minister may approach the courts for appropriate relief as it is the courts not committees that can pronounce on whether a decision was made in the public interest or not.

18

CLAUSE BY CLAUSE ANALYSIS OF THE BILL (1)

- Clause 1 seeks to amend the definition of "advertisement" to cover products, provide for the definition of "authority", "certification", "foodstuff" and "products".
- Clause 2 provides for the establishment and powers of the South African Health Products Regulatory Authority.
- Clause 3 provides for the appointment of the Chief Executive Officer and other staff of the authority.
- Clause 4 repeals sections 4, 5, 6, 7, 8, 9 and 12 of the principal Act.
- Clause 5 provides for the Chief Executive Officer to keep separate registers for products that are certified or registered.
- Clause 6 provides for the prohibition on the sale of products which are not certified or registered.

19

CLAUSE BY CLAUSE ANALYSIS OF THE BILL(2)

- Clause 7 deals with the certification and registration processes of health products.
- Clause 8 deals with the amendment of entries in registers of products that have been certified or registered.
- Clause 9 deals with the transfer of certification or of registration.
- Clause 10 seeks to amend section 15C of the principal Act to also provide for certification of products.
- Clause 11 deals with the process for cancellation of certification and registration.
- Clause 12 prescribes the process of the notification of certification and registration of products or cancellation thereof.
- Clause 13 deals with labels and advertisements of products.

20