Introduction to the Medicines and Related Substances Act, 1965 (Act 101 of 1965): **Setting the scene for Complementary Medicines Regulation**

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Medicines Control Council of South Africa

NDoH Vision & Mission

- **Vision**
  - A long and healthy life for all South Africans
- **Mission**
  - To improve health status through prevention of illness and the promotion of healthy lifestyles and to consistently improve the healthcare delivery system by focusing on access, equity, efficiency, quality and sustainability

POLICY & LEGISLATIVE FRAMEWORK

- National Drug Policy –access to safe, efficacious quality medicines & appropriate human resources
- 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

LEGISLATIVE POWERS & RESPONSIBILITIES

- **MINISTER**: Appointment of MCC, Appeal Committee, Pricing Committee and Promulgation of regulations
- **DIRECTOR GENERAL**: Release of Information, Issuing of Permits for Psychotropics & Narcotics, Licensing premises

PILLARS OF EFFECTIVE MEDICINE REGULATION (WHO)

- Existence of an **Independent** Medicine Regulatory Authority - MCC
- **Separation of powers**, Transparency & accountability
- **Registration of Medicines**: Quality, Efficacy, Safety.
- **Licensing**: Manufacturers, Wholesalers
- **Control Aspects**: Who may manufacture, distribute, prescribe, dispense, import, export, etc
- **Compliance with requirements** : Reporting of Adverse Reactions, Medicine recalls etc
- **Effective** law enforcement

PILLARS OF MEDICINE REGULATION *cont…*

- Sanctions and Penalties
- Information that may be published
  - Confidentiality Clause (Information for health professionals and for consumers)
- Control of Promotion, Advertising and Ethical Conduct
- Prohibitions, Exemptions and Special Approvals

BARRIERS TO EFFECTIVE REGULATION (WHO)

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

Who is the MCC?

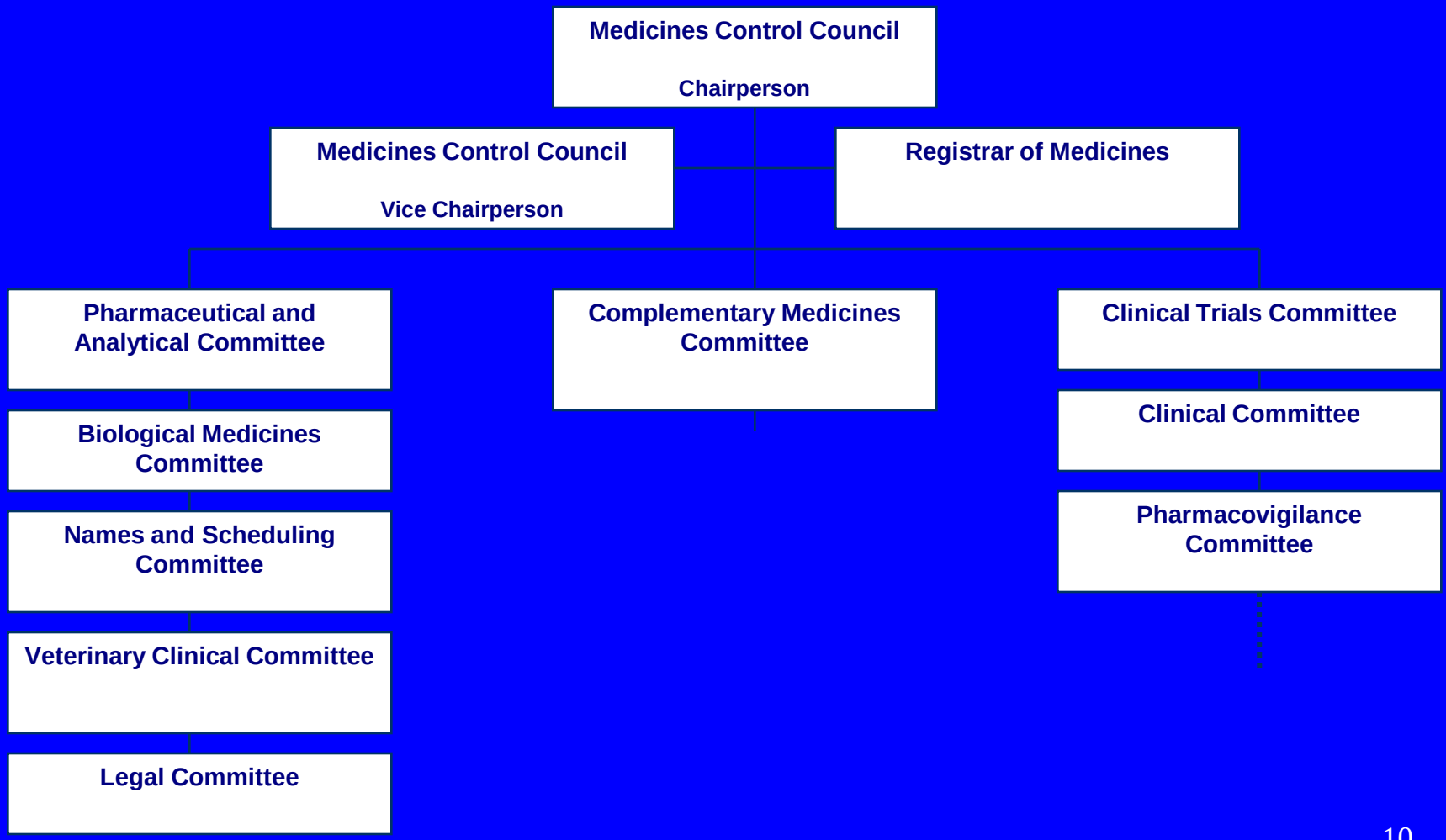
- Statutory body
  - Reporting to Minister of Health
  - No staff
- 24 Expert members

*Pediatrician
*Clinical pharmacology
*Pharmaceutical chemistry
*Toxicology & drug safety
*Agriculture
* Complementary medicines
*Virology & micro
*Veterinary clinical
*Internal medicine
*Public health
*Law

How does MCC Work

- Evaluators drawn from Academia, Research Institutions, Practice settings, very few in-house
- Nine Expert Peer Review committees meet at least every 6 weeks
- GMP /GCP inspections
- Sub committee working groups when necessary
- MCC every 6 - 8 weeks for decision making
- Registrar keeps register of medicines, licences etc.
- Registered products on MCC website

Medicines Control Council & Expert Committees



Obligations

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

MCC Mandate

- Registration of medicines based on safety efficacy and quality
- Approval of clinical trials
- Monitoring of safety
- Response to signals
- Licensing manufacturers, wholesalers and distributors
- Ensuring compliance
- Provision of information

Effective Medicine Regulation

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**

Some provisions of the Law

- Section 14 – Prohibition of sale of medicines which are subject to registration and are not registered (extemporaneous preparations allowed)
- Sell means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey, or deliver for sale, authorise, direct or allow a sale, or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; sale & sold shall have corresponding meanings.

DEFINITION OF A COMPLEMENTARY MEDICINE

- Any substance or mixture of substances which
  - originates from plants, minerals or animals;
  - is used or intended to be used for, or manufactured or sold for use in assisting the innate healing power of a human being or animal to mitigate, modify, alleviate, or prevent illnesses, or the symptoms thereof or abnormal physical or mental state, and
  - in accordance with the practice of the professions regulated under the Allied Health Professions Act, 1982 (Act No 63 of 1982)

Categories of medicines (Regulation 25)

Category D

- CAMs intended for use in humans and animals which are, without further manipulation, ready for administration, including packaged preparations where only a vehicle is added to the effective medicine

Disciplines of CAMs

- Chinese medicines
- Ayurveda medicines
- Unani Tibb medicines
- Homoeopathic medicines
- Aromatherapy medicines
- Western Herbal medicines

NEED FOR CONTROL OF CAMs

- **Minister of Health**: called for the registration of complementary medicines by amending the regulations to the Medicines Act on 15 November 2013.
- Thus there is a requirement for the MCC to evaluate and pronounce on the safety, quality and efficacy of these medicines

FLEXIBILITIES IN LAW

Section 21

- MCC may authorise sale of an unregistered medicine
- Authorisation in writing **to a person** to sell during a **specified period** to any **specified person** or institution a **specified quantity, purpose of the use** of such medicine
- Assumes treating practitioner will monitor patient closely, motivation why an unregistered medicine must be used
- **Patient must be informed** that the drug is **not registered** and
- **Sign *informed* consent form**, unused drugs to be returned to suppler for disposal, follow –up reports to be supplied to MCC and supplier

FLEXIBILITIES *cont.*

Section 36

-Exclusion of any drug from the operations of Act 101

-The Minister may, on the **unanimous recommendation** of the members present at any meeting of the council, **by notice** in the ***Gazette*** exclude, subject to such conditions as he may determine, any medicine from the operation of any or all the provisions of this Act and may in like manner amend or withdraw such a notice

FLEXIBILITIES *cont.*

Right to appeal

- Section 24 provides for anybody to appeal to the minister against any decision made by the MCC and the Director General

PRESERVATION OF SECRECY

Section 34

No person shall, except for

- The purpose of the exercise of his powers
- The performance of his functions
- For the purpose of legal proceedings
- When required to do so by any competent court
- Under any law
- With the written authority of the DG

PRESERVATION OF SECRECY *cont.*

- **Disclose to any other person** any information acquired by him in the exercise of his powers or the performance of his functions under this Act and
- Relating to **the business or affairs** of any person
- Or **use** such information for self-gain
- Or for the **benefit of his employer**

COMMON MISCONCEPTIONS

- CAMs are not medicines
- “Natural” medicines are safe
- MCC is insensitive to public needs
- MCC does not share information

UNPACKING MISCONCEPTIONS

- CAMs are medicines (Refer to definition in the Act)
- Natural medicines are not automatically safe
- Regulation of medicines is based on risk and decisions are made on scientific evidence
- Information on registered medicines, guidelines, processes etc. is on the website www.mccza.com

Conclusion

- Regulations and Guidelines are live documents that can be adapted as need arises
- Further information sessions and meetings will be held to clarify further questions

END

MCC WEBSITE:

- **www.mccza.com**

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