



DEPARTMENT OF HEALTH  
Republic of South Africa



# **LEGISLATION UPDATE & STATUS OF MCC / SAHPRA and GUIDANCE TO MEET REGULATOR'S EXPECTATIONS**

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Trade and Product Regulation**

**NATIONAL DEPARTMENT OF HEALTH**



# Outline

- Introduction
- Appointment of Council
- Organization
- SAHPRA
- Legislative update: Medical Devices, IVDs, API, CAMS
- Inspectorate: Standards of submissions and guidance for Improvement
- Institute of Regulatory Science (IRS)

# Introduction

- Regulation and control of medicines is not an option but an imperative for national health programs
- The challenge is to have the necessary policy, objectives and the legislative provision and adequate and appropriate human, financial, technical and physical resources supported by appropriate SOPs and policy guidelines



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# Policy Framework

## Health Objectives of the National Drug Policy

- Availability and accessibility of Essential Medicines to all citizens
- Treatment Guidelines for Health Personnel (EDL)
- Safety, Efficacy and Quality of medicines through evaluation, testing, registration and post-registration surveillance
- Good Dispensing and Prescribing Practices
- Rational Use of medicines
- Individual responsibility for Health, Preventive Care and Informed Decision Making



# Legislative Framework

- Medicines and Related Substances Act, 1965 (Act 101 of 1965)
  - Medicines Control Council
  - Registrar and Secretariat
  - Regulation and Control of Medicines , scheduled substances , Medical Devices
  - Licensing of Manufacturing, Storage and Distribution Facilities



# Elements of Act 101 of 1963



- Registration of Medicines
- Establishment of MCC – juristic entity
- Declaration of Commercial interest of members
- Control of medicines, scheduled substances, medical devices
- Prohibition of unregistered medicines
- Expedited registration of essential medicines
- Re-evaluation of medicines after 5 years
- Supply of more affordable medicines in certain cases
- Product labeling and consumer information
- Prohibition of sampling & bonusing
- Licensing of manufacturers, wholesalers, distributors
- Licensing of persons who compound & dispense
- Generic substitution
- Pricing Committee
- Regulation of Clinical Trials
- Regulate purchase & sale of medicines by licensees
- Appeals
- Fees
- Regulation power of Minister



# Medicines Control Council

- MCC established in terms of Act 101 of 1965
- Council consists of not more than 24 members (expertise of 14 members is defined) appointed by the Minister of Health
  - Chair & Vice-chair
  - Office of the Registrar of Medicines
  - Executive Committee
  - Expert Committees
- Secretariat of the MCC
  - Appointed by the Department of Health

# Qualification of Council (Regulation 35)

- Medical Practitioner & Public health
- Medical Practitioner & Paediatrics
- Medical Practitioner & internal medicine
- Pharmacist & pharmaceuticals and bioequivalence
- Veterinarian rep from DoA Agriculture
- Reg 35(a)
- Reg 35(a)
- Reg 35(a)
- Reg 35(f)
- Reg 35(j)



# Qualification of Council (Regulation 35)

- Complementary medicines
- Biotechnology
- Pharmaceutical Chemistry
- Virology & microbiology
- Adverse Drug Reactions
- Pharmaceutical Chemistry
- Law
- Veterinary clinical pharmacology
- Clinical pharmacology
- Reg 35(k)
- Reg 35(e)
- Reg 35(c)
- Reg 35(h)
- Reg 35(c)
- Reg 35(l)
- Reg 35(i)
- Reg 35(b)



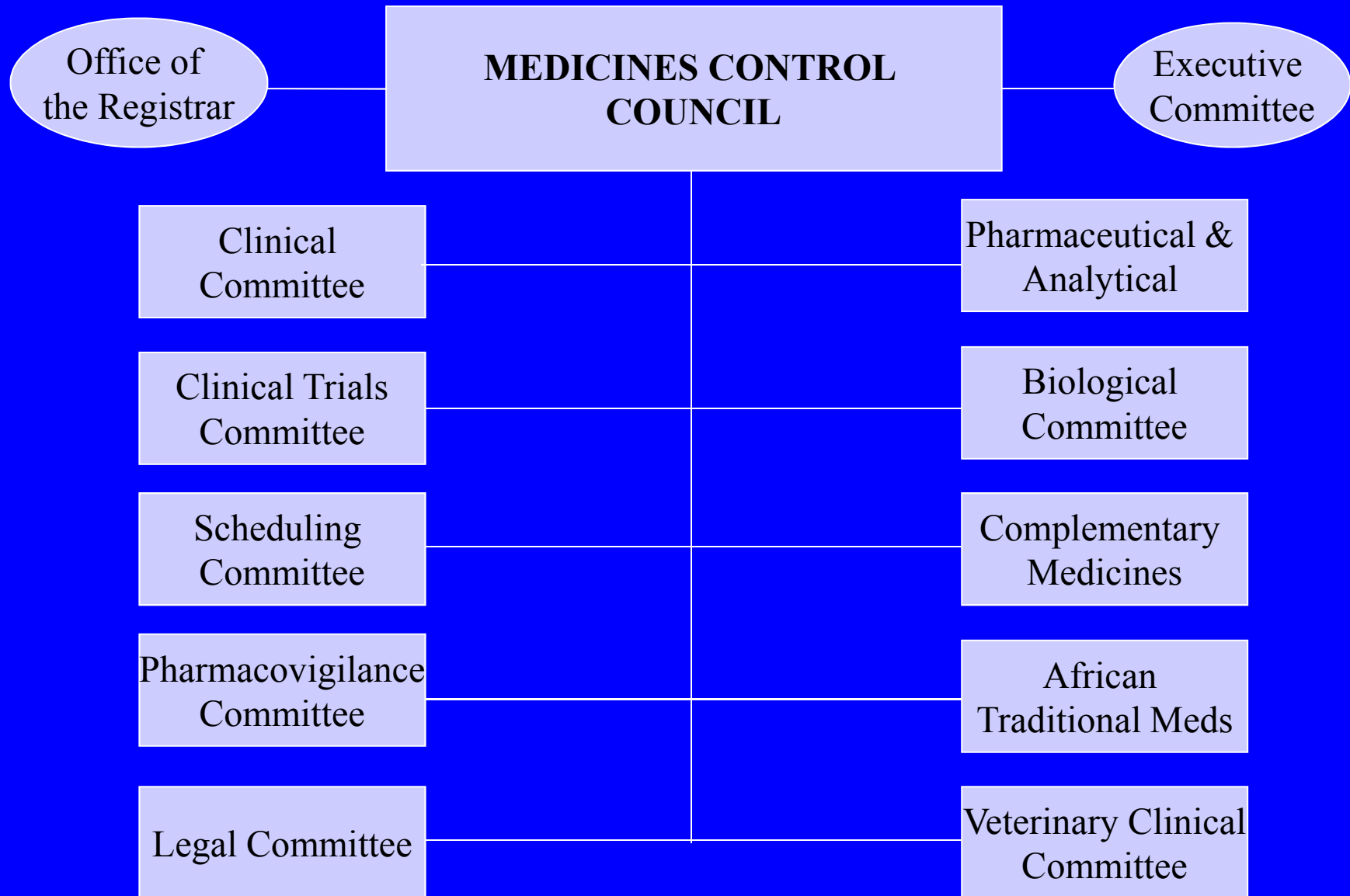
# Medicines Control Council



## Objectives and Functions

- Regulation in the public interest
  - Quality, safety & efficacy of medicines (QSE)
  - Appropriate prescribing information
- Efficient, effective, ethical evaluation & registration of medicines
- Transparent, fair, objective, timeous, and confidential decision-making
- Periodic reassessment & monitoring
- Adverse events & interactions monitoring
- Compliance with legislation – inspections and audits
- Clinical trial regulation

# Medicines Control Council & Expert Committees



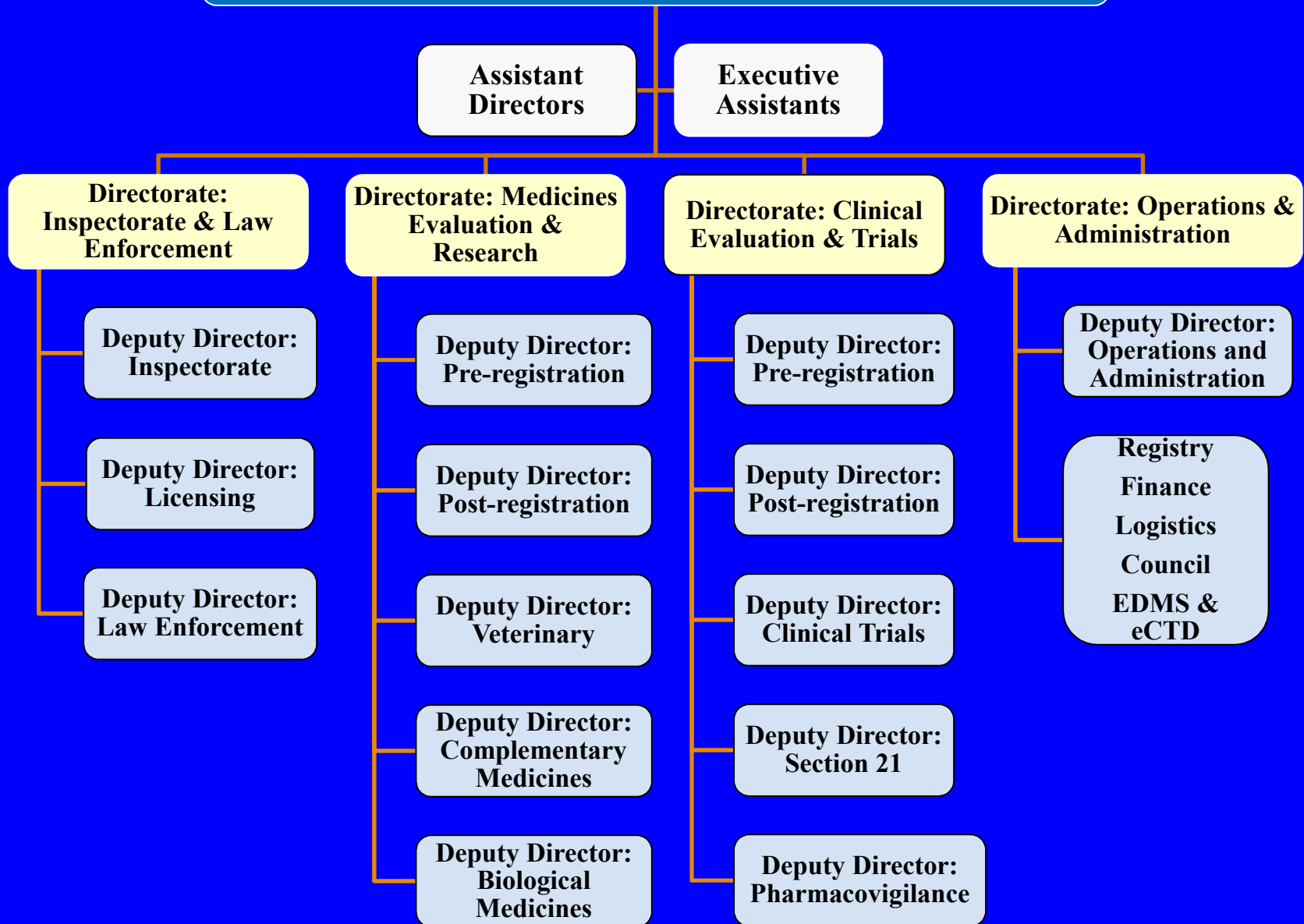


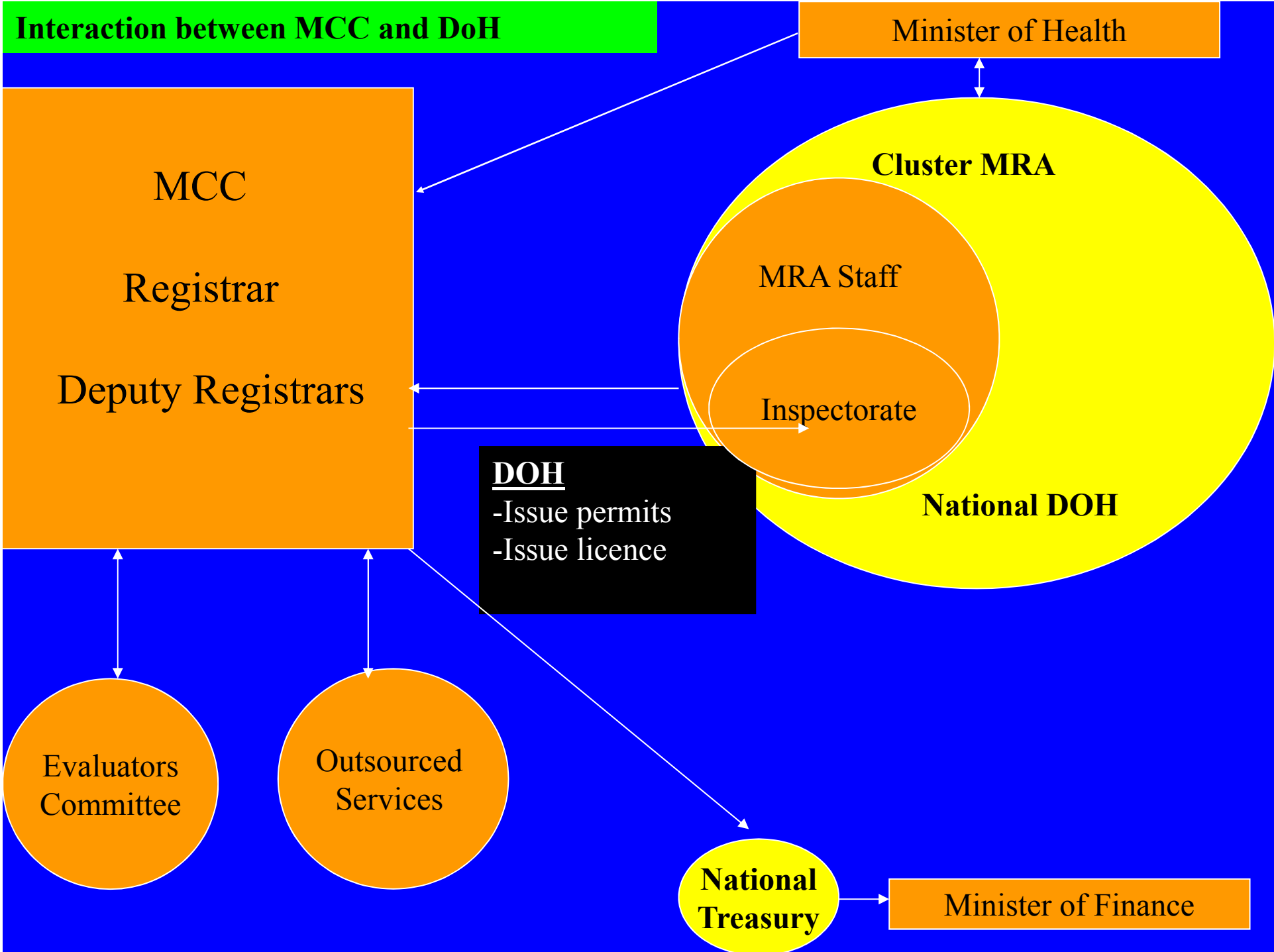
# Office of the Registrar of Medicines



- Registrar and provision for 2 Deputy Registrars;
- Office serves as Executive Secretary to the Medicines Control Council;
- Provides administrative and technical support for the MCC and its Expert Committees;
- Manage staff and activities of the Secretariat -
- Chief Directorate within the Department of Health - Cluster: Pharmaceutical and Related Product Regulation & Management and also oversees Food and Radiation Control Directorates

# Registrar of Medicines and Cluster Manager







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# South African Health Products Regulatory Authority (SAHPRA)



- Amendment to Medicines Act passed in 2008 establish new Authority (SAHPRA) to replace the MCC. Not implemented as yet.
- Amendment Bill (Bill 6 of 2014) in Parliament to address transition.
- SAHPRA = juristic entity, independent of NDoH, responsible to Minister & compliant with the Public Finance Management Act (PFMA).
- Board of SAHPRA have governance and fiduciary duties.



# South African Health Products Regulatory Authority (SAHPRA)



- Board appoint Chief Executive Officer (CEO)
- CEO appoints Committees to assist with work of Authority
- Regulatory framework will include medicines, API's medical devices, IVD's.
- Authority registers medicine, Medical Devices and IVDs
- SAHPRA employ own staff and retain fees for services.



# South African Health Products Regulatory Authority (SAHPRA)

MINISTER

SAHPRA – Section 3A public entity

BOARD

Risk Audit  
Committee (PFMA)

Administrative

Chief Financial Officer

Executive Manager: Corporate  
Services

CEO

Technical Support (Executive  
Manager)

Authorization Management

Inspectorate And Regulatory  
Compliance

Regulatory

Medicines

Medical Devices and  
Diagnostics (Inc IVDs &  
Radiation Control)

Complementary  
Medicines



# Legislative update: Medical devices, *IVDs*, APIs, CAMS



- **Regulations and Guidelines to control Medical Devices and *IVDs***
  - Published
  - Stakeholder comment
  - Re publish for 1 month comment (post April 2015)
  - Workshop with Stakeholders (May-June 2015)
  - Publish for implementation



# Legislative update: Medical devices, IVDs, APIs, CAMS



- Regulations to control CAMS (2014-2019)
- Proposed definition for CAMS (Nov 2014)
  - Stakeholder comments
  - Workshop 30 March 2015
  - Publication for Implementation
- Bill 6 of 2014: Section 22C(1)(b) to license API
  - Importers
  - Wholesalers
  - Manufacturers

# **Inspectorate: Standards of submissions and Guidance**

# Inspectorate: Standards of submissions

- **Implementing corrective actions without establishing the root cause**

*for example: “the powders in the production corridor has been cleaned” with no investigation done to establish why there were powders*

- **Inadequate assessing of the effectiveness or impact of corrective actions**



# Inspectorate: Standards of submission



**...cont**

- **Lack of preventative measures to prevent recurrence of events**

*for example: processes are improved, but personnel not trained on the new processes*

- **Implementing corrective actions without following adequate procedures**

*for example: corrective actions are not implemented via change control*

## Inspectorate: Standards of submissions and guidance for Improvement ...cont

- Providing unreliable, unrealistic and misleading timelines

*for example: claiming completion with only a quote or an order, or only protocols have been drawn up and no results and reports, or equipment has been installed but not qualified, etc.*

# Inspectorate: Standards of submissions and guidance for Improvement

- **Responses are not implemented**

*for example: when a follow-up inspection is performed, CAPA's indicated in the responses are found not to be implemented*

- **Providing misleading responses**

*for example: providing a picture as evidence for new pressure gauges to replace the non compliant ones, or to show it is calibrated, but only one was purchased and calibrated for the purpose of the response*





# Inspectorate: Standards of submissions and guidance for Improvement

- Rather than responding, MCC observations compared with other NRAs

*for example: “we were inspected by the FDA last week, with no, or no critical observations” or “the TGA did not require for us to implement quality control separate from production areas” and “We believe that the alleged deficiencies identified in the report and the subsequent classification thereof in Critical and Major Deficiencies is done in an arbitrary manner”*

# Inspectorate: Standards of submissions

## ...cont

- **The use of risk assessments to avoid compliance**  
*for example: using the fact that the products handled on the site is only S0 or complementary and therefore there is no need for all GMP requirements.*

# Inspectorate: Standards of submissions

## ...cont

- **The use of delay tactics to provide responses on time**

*for example: “travelling at the moment, can only respond on return”*

- **Inadequate or no supportive documents provided**

*for example : “SOP now exist”, “Information now available for inspection”*



# Inspectorate: Standards of submissions

## ...cont

- **Poor understanding of MCC processes**  
*for example: expecting a license to be issued immediately after the response was submitted*



# Inspectorate: Guidance for Improvement

- **Guideline on How to Respond to a GMP or GWP Inspection Report’ was drafted**
  - *To be discussed at the next Inspectorate P&A meeting to be held 31 March 2015*
  - *Anticipate to be published on the MCC website for industry to comment after the next MCC meeting*



# MCC/SAHPRA Guidance for improvement

- Establishment of Institute of Regulatory Science
- Within MCC/SAHPRA
- Virtual University for RSA, SADC, Africa
- Students: Regulatory staff from NRA, Industry etc
- Best practices from various universities, local and international



# WORKING TOWARDS SAHPRA!

## MCC WEBSITE:

- [www.mccza.com](http://www.mccza.com)

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