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A GLIMPSE OF WHAT SAHPRA IS INTENDED TO BECOME

SACRA'S 3RD ANNUAL CLINICAL TRIAL
CONFERENCE
BIRCHWOOD HOTEL AND CONFERENCE
CENTRE
27-28 AUGUST 2009

DR NICHOLAS CRISP

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The MCC's mandate

- Registration of medicines (human and animal) based on quality safety and efficacy
- Control of medical devices (covered in the Act but not provided for in regulations)
- Approval and monitoring of clinical trials
- Monitoring of safety
- Response to signals
- Licensing of manufacturers, wholesalers and distributors

MCC's obligations

- Ensuring public safety
- Ensuring public protection
- Ensuring transparency in its processes
- Accountability to the public, the clients (industry and providers) and the public
- Responsiveness to the environment
- Risk assessment i.e. minimisation of harm and maximization of benefit

Medicines Control Council

- Council
- Committees

MEDICINES CONTROL COUNCIL

Clinical Committee

Pharmacovigilance
Committee

African Traditional
Medicines

Complementary
Medicines

Scheduling
Committee

Biological
Committee

Pharmaceutical &
Analytical

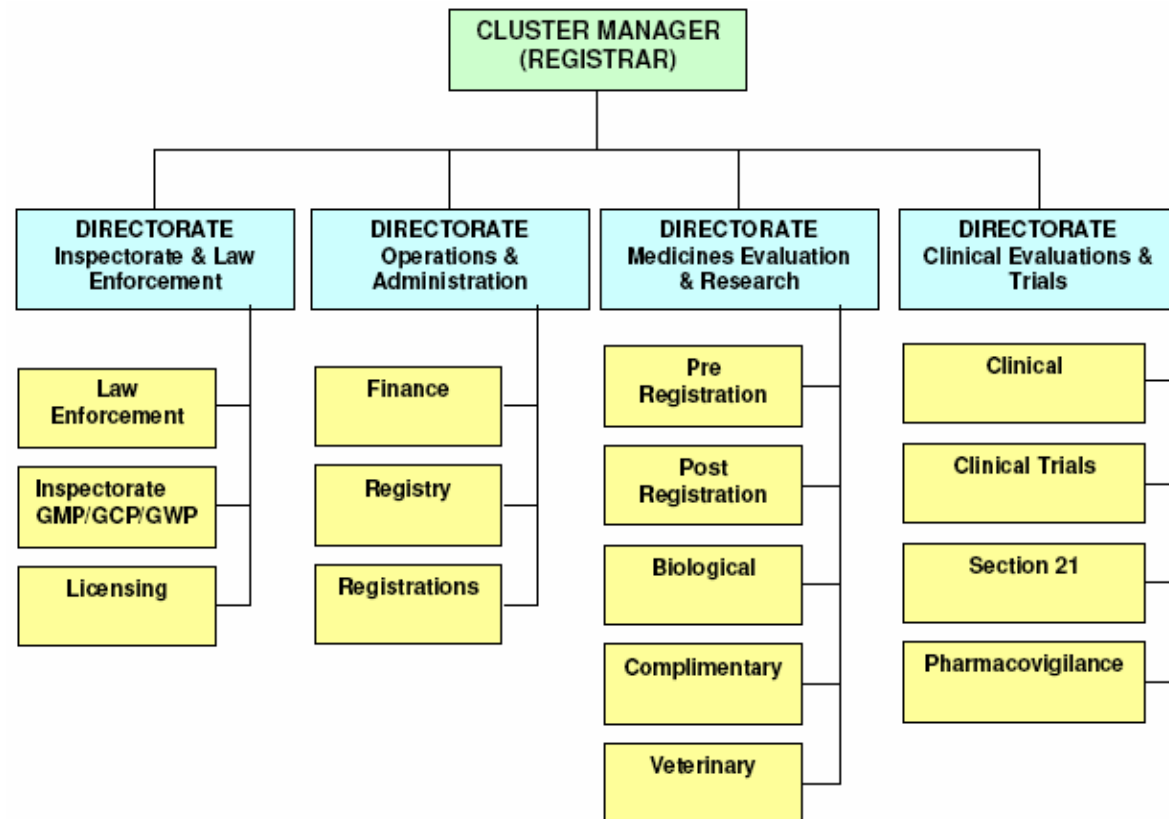
Clinical Trials
Committee

HIV Vaccine trials
Committee

Veterinary Clinical
Committee

Cluster: Pharmaceutical and Related Product Regulation & Management

- Registrar
- MRA



Possible Future

- Independent public entity
 - Board appointed by Minister but replaces Minister
 - Committees of Board (technical and governance)
 - CEO and Executives appointed by Board
- Own buildings, IT, personnel and other systems
- Own revenue generation, retention and management
 - Minister of Health and Treasury approve tariffs

Possible Structure

- Health Products
 - Medicines (and Biologicals, including complementary and traditional)
 - Devices (assessment and regulation)
- Separate Regulatory Councils and Committees
- Single Board of Management

Early days - Process

- SAHPRA consultation and document
- Technical Task Team consultation and report
- Needs a Project Plan
 - What will it look like?
 - What will it cost?
 - Can it generate its own funds?
 - Seed capital from where?
 - Personnel remuneration system, skills and numbers?
 - IT solutions?
 - Legal requirements?
 - Where should it be located?
 - Document management?

More process

- Timeframes??
- Consultation process
 - Internal
 - External
- Statutory process
- Budget cycle and financial compliance
- Etc

We have a long way to go



Questions



Travel safely

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