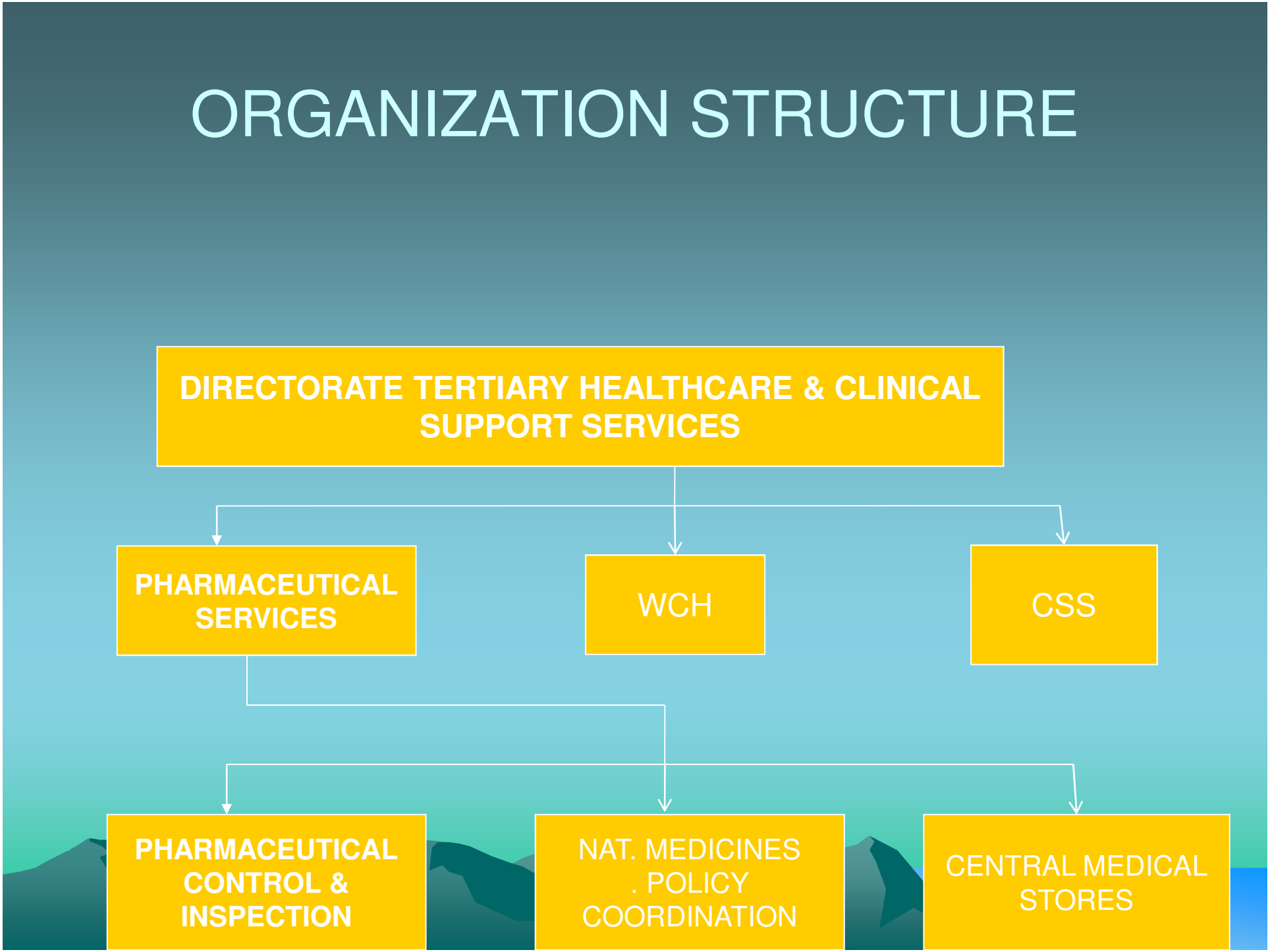
PHARMACEUTICAL CONTROL & INSPECTION

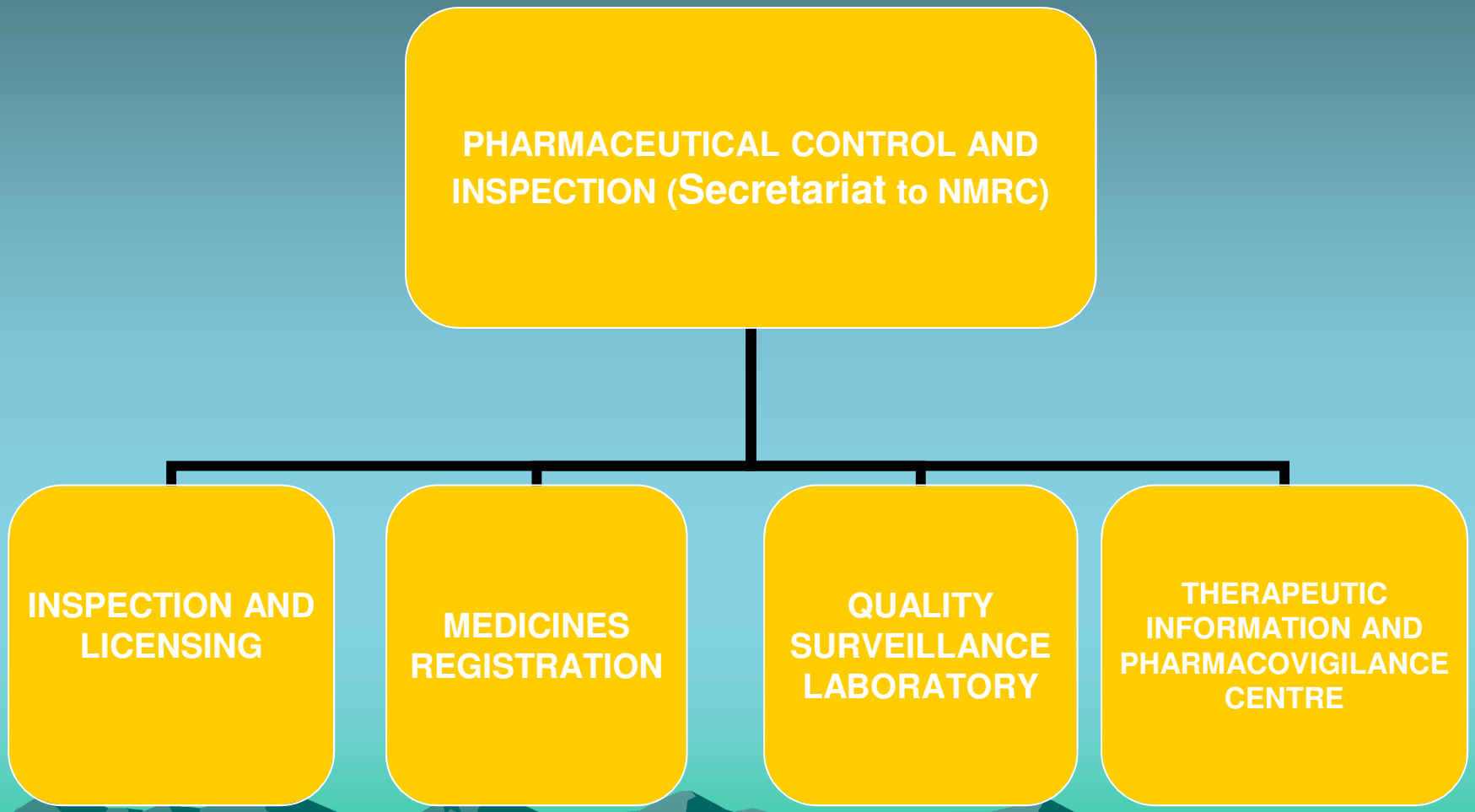
SAPRAA MEETING

18 MARCH 2011

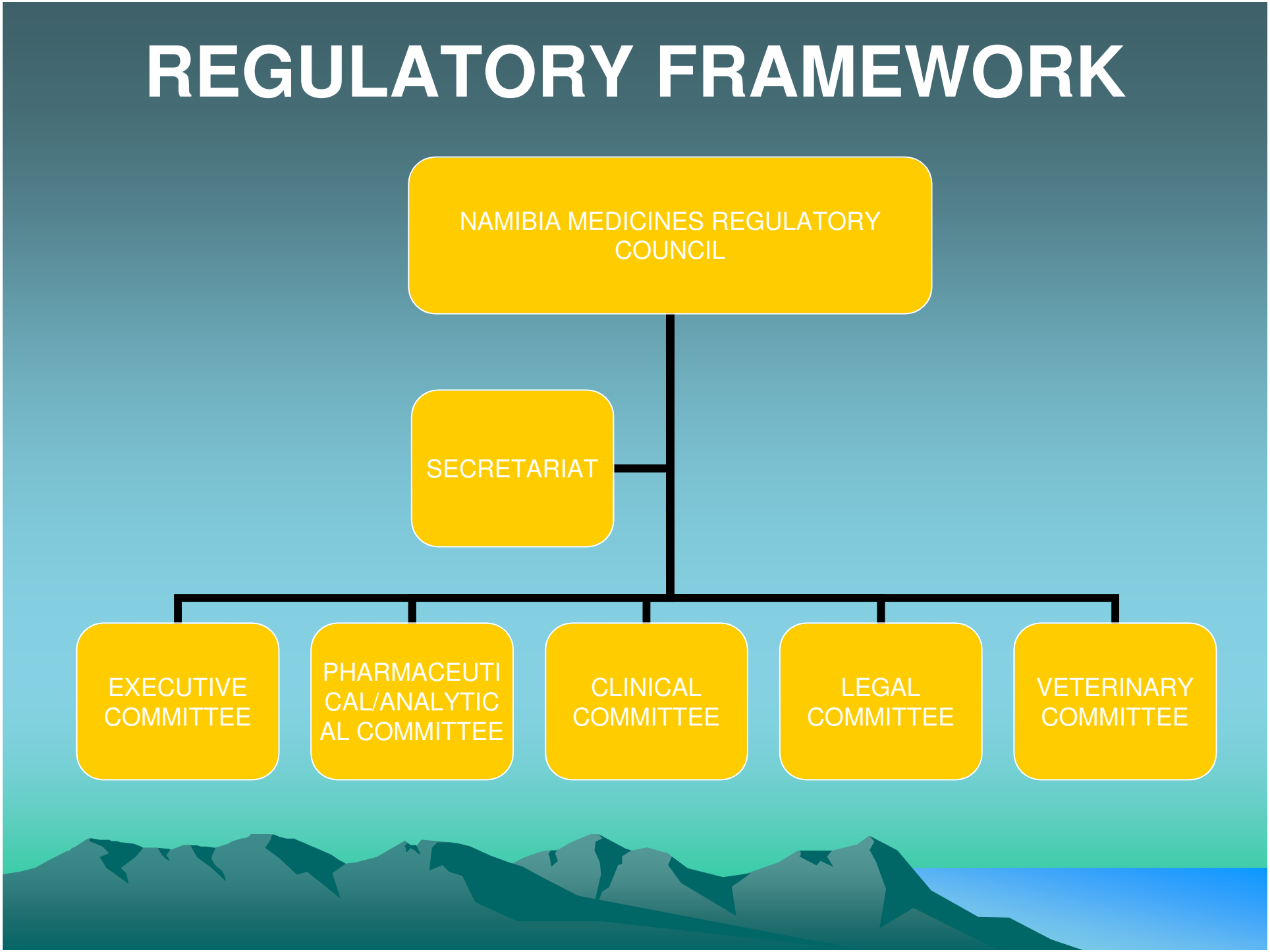
ORGANIZATION STRUCTURE



ORGANIZATIONAL STRUCTURE (CONT.)



REGULATORY FRAMEWORK



THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, ACT 13 OF 2003

- PROVIDES FOR THE ESTABLISHMENT OF THE NAMIBIA MEDICINES REGULATORY COUNCIL (NMRC)

- THE NMRC MAKES DECISIONS INDEPENDENTLY AND REPORTS DIRECTLY TO THE MINISTER, BUT IS NOT FINANCIALY AUTONOMOUS.

Functions (1)

- Registration Section
  - Medicines registration
    - Dossier receipt, screening for completeness
    - Entering dossier into data base, allocation of application number
    - Evaluation of dossiers
    - Communication with applicant on findings (rejection, more information, accepted etc)
  - Reporting to Pharmaceutical Analytical Committee

Functions cont. (2)

- Recommendation to Council to register certain products
- Maintaining the Register:
  - discontinued products,
  - deleted products for non-compliance,
  - recalls etc
- Handling applications for amendments such as change of applicant, change of manufacturing facilities, change of analytical procedures, change of process, procedures etc.

Functions cont. (3)

- Inspection & Licensing Section
  - Inspection for compliance with Medicines & Related Substances Control Act no.13 of 2003:
    - All hospitals (public and private)
    - Pharmacies
    - Dispensing Doctors
    - Clinics
  - GMP Inspection of Pharmaceutical manufacturers

Functions (4)

- Control of narcotic medicines in Health Facilities
- Inspection of wholesalers and distributors
- Ensure that only registered medicines are on the market in Namibia

- THERAPEUTICS INFORMATION AND PHARMACOVIGILANCE CENTRE
- QUALITY SURVEILLANCE LABORATORY
- Development of policy framework

NEW DEVELOPMENTS

- New Act in place since August 1st 2008
- There are discussions to make the NMRC a cost centre.

Ramifications of the new Act

POSITIVE ASPECTS

- We have new fees payable to the Registrar for services provides by NMRC.
- Quality of submitted dossiers has improved.
- Backlog for dossiers awaiting evaluation has been reduced.

Ramifications cont.

- NEGATIVE ASPECTS
- Section 31(1), 31(2) and 31(3) is being challenged in the court of law.

Ramifications cont.

- Labelling requirements in line with the requirements of the new law could not be implemented immediately.
- An implementation delay has been approved and gazetted.
- Cancellations of registration of old / not selling products is now very common.

SCHEDULE 3 - 5 MEDICINES

- Also under the control of the International Narcotics Control Board.
- Countries are required to submit annual estimates
- Importers require an import permit, which is a prerequisite for an export permit in the exporting Country

PHARMADEX

- This is a medicines registration database.
- It is currently under review to make it a fully integrated Medicines Regulation Tool covering all services provided by the NMRC Secretariat.

CHALLENGES

- Shortage of human resources
- Relocation of the TIPC
- Space constraints of the QSL

NAMIBIA MEDICINES CONTROL ACT

WHAT SAPRAA WANTS TO KNOW

LABELLING REQUIREMENTS

- The following are to be on label:
  - Registration number given by NMRC
  - Namibian scheduling status
  - Both manufacturing and expiry dates must be on label

- COUNCIL RESOLUTION:
  - Exempt the manufacturing site information and manufacturing date
  - Require the submission of site master file

- Deadline to comply extended to 30th April 2012

GUIDELINES

- The following guidelines are being drafted:
  - Post registration amendments
  - Medicines recall/withdrawal
  - Supply of unregistered medicines to a patient (Compassionate clearance)
  - Marketing of Medicinal products
  - Import/export licencing
  - Section 31 licenses
  - Medical representatives
  - Complementary medicines
  - Pharmacovigilance

MEDICINES APPLICATION FORM

- MRF1 still in place
- CTD format under consideration

LOCAL REPRESENTATIVE

- All marketing authorization holders not based in Namibia must appoint a representative based in Namibia.
- Reviewing Act to include punitive action against non-compliance

IMPORT OF MEDICINES

- Any company wishing to import any medicines (including schedule 0) require a license
- Importation of medicines restricted to Pharmaceutical Wholesalers for products of schedules higher than 0
- Schedule 0 medicines maybe be imported by non- pharmaceutical wholesalers

CONTACT DETAILS

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THANK YOU FOR YOUR ATTENTION