

MEDICAL CONTROL COUNCIL-MCC

Rasmita Jena
Assistance Professor
SoPLS, CUTM, BBSR

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Medicines Control Council



- **Introduction:-3,V**
- South Africa has developed a medicines regulatory authority with internationally recognized standing.
- The Medicines Control Council (MCC) is a statutory body that was established in terms of the Medicines and Related Substances Control Act, 101 of 1965, to oversee the regulation of medicines in South Africa.

HistoryV



- more than 20 000 medicines have been approved.
- more than 220 meetings have been held to decide on the registration of medicines.
- The South African Pharmacy Council has licensed 300 wholesalers and distributors.
- The Medicines Control Council approves more than 280 clinical trials annually

Regulatory Program 3,V



- The Medicines Control Council applies standards laid down by the Medicines and Related Substances Control Act, (Act 101 of 1965) which governs the manufacture, distribution, sale, and marketing of medicines.
- The prescribing and dispensing of medicines is controlled.
- The Council has eleven technical committees, with 146 members from various institutions in the country.

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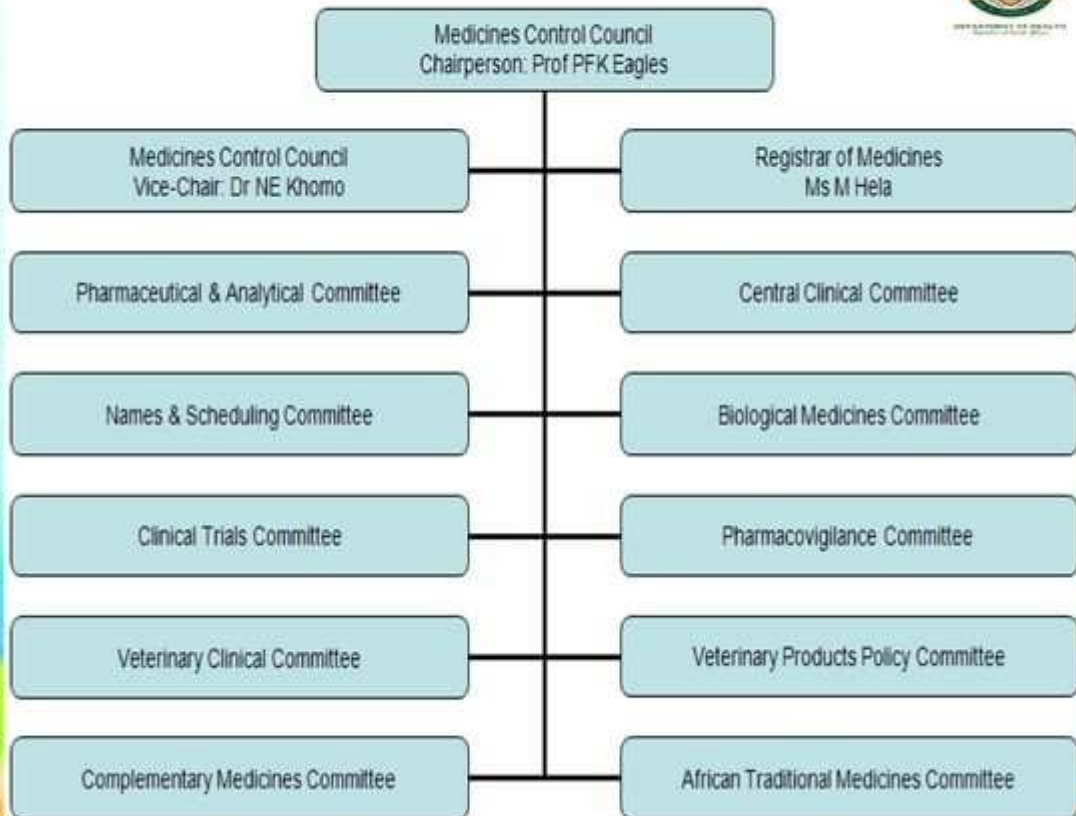
- The MCC operates through external experts who are members of Council Committee structures. Most experts evaluate data sets submitted by the pharmaceutical industry for purposes of registration.
- The office of the Registrar provides administrative and technical support to Council and its activities. The Registrar is also an executive secretary to Council.



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- The staff complement of Medicines Regulatory Affairs includes doctors, pharmacists, veterinarians, other scientists and administrative staff.
- The skills of Council and its committees are written into law and include expertise in toxicology and medicine safety, clinical pharmacology, biotechnology, pharmaceuticals, internal medicine, virology, pharmaceutical chemistry, neonatology, pediatrics, immunology, veterinary science, complementary medicines and law.

MEDICINES CONTROL COUNCIL & EXPERT COMMITTEES



GuidelinesV



Good Manufacturing Practices:-

- Guidelines on inspections involving the Gmp inspectors
- Isolator technology
- Penicillin manufacturing
- Radiopharmaceutical manufacturing
- Aerosol manufacturing
- Guidelines for preparation of site master file

Conclusion

- The Regulatory system for complementary medicines must continue to ensure that the medicines having highest possible level of confidence in their overall safety and quality.
- The current system of regulation of complementary medicines allows consumers to have faith in the quality, safety and efficacy of medicines.

THANK YOU

