SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA CEO TECHNICAL ADVISORY COMMITTEES

An overview of technical committees established in terms of Section 3(5) of the Medicines and Related Substances Act, 101 of 1965

Overview of the CEO's TACs

The CEO Technical Advisory Committees (TACs) provides regulatory technical expert advisory in the form of recommendations, to the Authority/CEO on matters referred to it by either internal evaluators or external evaluators.

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Introduction

Overview of SAHPRA

The South African Health Products Regulatory Authority (SAHPRA) is mandated to oversee the regulation of health products in the country. SAHPRA is an entity of the National Department of Health, created by the South African government to ensure that the health and well-being of human and animal health are at its core. SAHPRA is a Schedule 3A public entity that is responsible for:

- the regulation of health products intended for human and animal use;
- the licensing of manufacturers, wholesalers, and distributors of medicines and medical devices; radiation emitting devices and radioactive nuclides;
- the conduct of clinical trials in a manner that is compatible with the national medicines policy.

Role of the CEO Technical Advisory Committees

The CEO appoints suitably qualified external experts to assist SAHPRA in its functions, as mandated by section 3 (5) of the Medicines and Related Substances Act, , 1965 (Act No. 101 of 1965) as amended, the CEO shall appoint suitably qualified staff and may contract other suitably qualified persons to assist the Authority in carrying out its functions. The CEO Technical Advisory Committees (TACs) play a crucial role in providing regulatory advice and make recommendations to the Authority on various regulatory matters.

CEO Technical Advisory Committees

Overview

The CEO Technical Advisory Committees provide regulatory advice to the SAHPRA CEO. These committees review applications, and make recommendations to SAHPRA on regulatory matters.

List of Advisory Committees

- Clinical Trials
- Clinical
- Names & Scheduling
- Pharmacovigilance
- Pharmaceutical & Analytical
- Biological Medicines
- Complementary Medicines
- Veterinary Medicines
- Medical Devices & IVDs
- Good Practices Compliance (GxP)
- Radiation Control
- Legal

Clinical Trials Committee

Objectives

The Clinical Trials Committee provides advice on the authorisation and oversight of clinical trials conducted on human participants and animals.

Scope and Functions

- Review of clinical trial applications.
- Recommendations on the design and conduct of clinical trials.
- Evaluation of scientific and ethical standards.
- Ensuring compliance with the South African Good Clinical Practice (GCP) guidelines.

Expertise

- Cardiology
- Paediatrics
- Public Health
- Clinical Pharmacology
- Clinical Pharmacy
- Pre-clinical Toxicology
- Pathology
- Microbiology
- Virology
- Oncology
- Psychiatry
- Gynaecology
- Statistics
- Other medical sub-specialities

Clinical Committee

Objectives

The Clinical Committee advises on the safety, efficacy and overall benefit-risk profile of medicines to ensure that they meet established standards for therapeutic use.

Scope and Functions

- Review and recommend medicines for registration based on clinical efficacy and safety data.
- Conduct continuous assessment of approved medicines for ongoing safety and effectiveness.
- Review of amendments to professional information and patient information leaflets.
- Review and update clinical evaluation guidelines to align with best practices and regulations.
- Recommend cancellation or restrictions of medicines when new evidence show safety or efficacy concerns.

Expertise

- Clinical disciplines of medicine
- Surgery
- Anaesthesia
- Clinical pharmacology
- Pharmacovigilance

Names and Scheduling Committee

Overview

The Committee advises on the scheduling status of medicines, as well as the evaluation and approval of proprietary names.

Scope and Functions

- Review and determine the scheduling status of medicines and vaccines. Amendments to existing schedules.
- Review of recommended names.
- Review and recommend prescribing rights for authorised prescribers.

Expertise

- Basic and Molecular Pharmacology
- Applied and Clinical Pharmacology
- Clinical Medicine
- Pharmaceutical Chemistry
- Medicine Information and Safety
- Community Pharmacy Practice
- Epidemiology
- Public Health Policies
- Veterinary Medicine
- Chemistry (Narcotics Enforcement)

Pharmacovigilance Committee

Overview

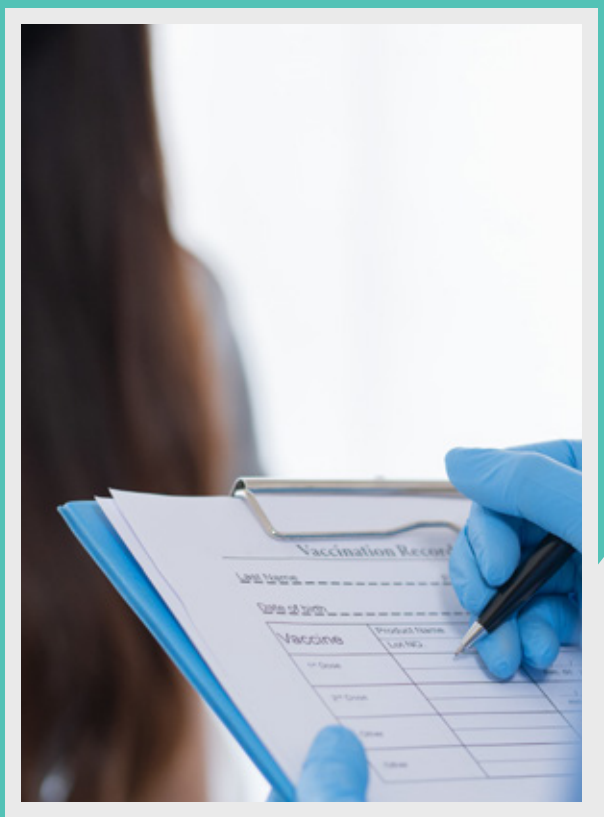
The committee supports the monitoring of the benefit-risk (safety-to-efficacy) balance of human medicines and vaccines throughout their lifecycle.

Scope and Functions

- Review and analyse medicines and vaccines safety data and make recommendations.
- Monitoring post authorisation safety of both medicines and vaccines.
- Review and make recommendations on medicine safety communications.

Expertise

- Internal/Clinical Medicines
- Clinical Pharmacology/Pharmacy
- Paediatrics
- Vaccinology
- Complementary Medicines
- Pharmacovigilance



Radiation Control Committee

Overview

The general objective of the committee is to make recommendations to the Authority on matters of regulatory oversight regarding ionising and non-ionising radiation-emitting devices and radioactive nuclides.

Scope and Functions

- Regulatory oversight for ionising and non-ionising radiation-emitting devices and radioactive nuclides.
- Safety signals made available by other bodies or from local data.
- Vigilance activities.
- Legal issues regarding the Hazardous Substances Act, 1973 (Act No. 15 of 1973), as amended.
- Approval or non-approval for the registration and licensing of ionising and non-ionising radiation-emitting devices and radioactive nuclides.
- Cancellation of previously approved and listed ionising and non-ionising radiation-emitting devices and radioactive nuclides.
- The safety of ionising and non-ionising radiation-emitting devices and radioactive nuclides.
- Ensuring that clinical trials, proficiency testing, and validation studies conducted with ionising and non-ionising radiation-emitting devices and radioactive nuclides are designed and conducted.
- The classification and reclassification of ionising and non-ionising radiation-emitting devices.

Expertise

- Medical Physics
- Radiography
- Clinical Engineering
- Biomedical Engineering
- Clinical Pathology
- Biomedical Technology
- Medical Laboratory Technology (with relevant knowledge and experience with ionising and non-ionising radiation-emitting devices and radioactive nuclides.
- Regulatory control and understanding of ionising and non-ionising radiation-emitting devices and radioactive nuclides, especially international requirements such as those from the International Atomic Energy Agency (IAEA).

Pharmaceutical and Analytical Committee

Overview

The committee advises on regulatory matters related to pharmaceuticals and bioavailability.

Scope and Functions

- Review and make recommnedations of the quality and manufacturing of medicines.
- Review guidelines on manufacturing and control of APIs and FPPs.

Expertise

- Pharmaceutics
- Pharmaceutical Chemistry
- Bio-statistics
- Biopharmaceutics
- Good Manufacturing Practices (GMP)

Biological Medicines Committee

Overview

The Committee advises on regulatory matters relating to biological products and vaccines.

Scope and Functions

- Evaluation of safety, efficacy, and quality of biological products.
- Review of guidelines for evaluation.
- Recommendations on biosimilar medicines.

Expertise

- Biological Medicines
- Blood product technology
- Immunology
- Microbiology
- Vaccinology
- Biotechnology

Complementary Medicines Committee

Overview

The committee advises on matters pertaining to Complementary Medicines (CMs).

Scope and Functions

- Review of registration applications for CMs.
- Recommendations on quality, safety, and efficacy.
- Research on CMs.

Expertise

- Traditional disciplines of CMs
- Health supplements
- Clinical trials and evaluation of CMs
- Manufacture and retail of CMs

Veterinary Committee

Overview

The committee advises on regulatory matters related to veterinary health products.

Scope and Functions

- Evaluation of veterinary medicines.
- Compilation of guidelines for veterinary products.
- International collaboration on veterinary product registration.

Expertise

- Species specialists for companion animals and wildlife
- Herd health and epidemiology
- Veterinary pharmacology and toxicology
- Agricultural and Health Department representatives

Medical Devices and IVDs Committee

Overview

The committee advises on the regulatory oversight of medical devices and IVDs.

Scope and Functions

- Registration and safety of medical devices.
- Licensing of medical device establishments.
- Monitoring safety signals and vigilance activities.

Expertise

- Clinical Engineering
- Biomedical Engineering
- Clinical Pathology
- Regulatory control of medical devices
- Conformity assessment of medical devices

Good Practices Compliance (GxP) Committee

Overview

The csommittee ensures compliance with good practices required by SAHPRA and international bodies.

Scope and Functions

- Review of inspection reports.
- Recommendations on compliance with GxP standards.
- Licencing and renewal of sites.

Expertise

- Good Clinical Practice (GCP)
- Good Distribution Practice (GDP)
- Good Laboratory Practice (GLP)
- Good Manufacturing Practice (GMP)
- Good Pharmacy Practice (GPP)
- Good Regulatory Practice (GRP)

Legal Committee

Overview

The general objectives of the committee are to provide support for the CEO on legal regulatory matters concerning the Authority; and advice relating to the legislated mandate of the Authority.

The committee shall provide advice, in the form of recommendations, to the Authority on matters referred to it or on such matters having legal implications for SAHPRA as it pertains to its legislated mandate, and as it may consider appropriate.

Scope and Functions

- Review legal challenges to legislation.
- Review of the regulations prior to recommendations to the Minister of Health.
- Interpretation of the Medicines Act and related regulations and the Hazardous Substances Act, 1973 (Act No. 15 of 1973), as amended.

Expertise

- Health Product Regulation
- Medical Law
- Pharmacy Law
- Administrative Law
- Knowledge and application of the Medicines Act and related regulations, the Hazardous Substances Act, 1973 (Act No. 15 of 1973), as amended, and related regulations.

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