SAHPRA
South African
Health Products
Regulatory Authority

GOOD REGULATORY PRACTICE

Lydia Motlogelwa

- Regulatory system
  - Regulatory Authority
  - Regulatory framework /legal framework
  - GRP principles & enablers
  - Implementation of GRP

SAHPRA
South African
Health Products
Regulatory Authority

REGULATORY SYSTEM

- Affordable health care products that are safe, effective/performance & assured quality
- Prevention, diagnosis & treatment of diseases
- Regulatory body/bodies (NRAs)

SAHPRA
South African
Health Products
Regulatory Authority

REGULATORY FRAMEWORK

Mandate: RAs
Authorised/Prohibited be haviour
(Products, Persons or action to be controlled)
Enacted legislative branch of government

LAWS

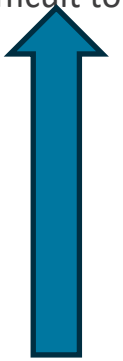
High level conditions to be met

REGULATIONS

Details on how the conditions can be met

GUIDELINES

Less flexible
Prescriptive
Most difficult to change



Detail
Flexible
Less prescriptive
Easy to change

SAHPRA
South African Health Products Regulatory Authority

PRINCIPLES AND ENABLERS OF GRP

GRP principles

- Legality
- Consistency
- Independence
- Impartiality
- Proportionality
- Flexibility
- Clarity
- Efficiency
- Transparency

GRP enablers

- -Political & government support
- -Good organization, governance & leadership
- -Effective communication, Collaboration& coordination
- -Robust and well functioning QMS
- -Sufficient and sustainable financial resources
- -Competent human resources
- -Preset organizational ethics & values
- -Science & data driven regulatory decision-making process

Regulatory system

Reg Framework:
1. Laws & regulations
2. Guidelines & guidance document

Regulatory Institutions
NRA, NCL, Vigilance Centre, Research ethics committee &Others

Resources:
HR, FR, equipment infrastructure, IMS

Regulatory functions/activities:
MA, Regulatory inspection & Vigilance

Regulatory Output:
Inspection, Assessment report, reg decisions, approved product label/info

Regulatory outcome:
Enhanced compliance with regulatory requirements

Regulatory Impact:
Access to health product that are safe, effective/perform as intendent & qualified quality. Less substandard or falsified health products. Increased contribution of the health system to the Country's economic revenue

SAHPRA
South African Health Products Regulatory Authority

PRINCIPLES OF GRP

Legality	Regulatory systems and the decisions of sound legal basis
Consistency	Regulatory oversight of medical/health products should be consistent with existing government policies and legislation and be applied in a consistent and predictable manner.
Independence	Institutions that execute regulation of medical products should be independent.
Impartiality	All regulated parties should be treated equitably, fairly and without bias
Proportionality	Regulation and regulatory decisions should be proportional to risk and to the regulator's capacity to implement and enforce them
Flexibility	Regulatory oversight should not be prescriptive but rather be flexible in responding to a changing environment and unforeseen circumstances. Timely responsiveness to a specific need and in particular to public health emergencies should be built into the regulatory system.
Clarity	Regulatory requirements should be accessible to and understood by users.
Efficiency	Regulatory systems should achieve their goals within the required time and at reasonable effort and cost. International collaboration promotes efficiency by ensuring the best use of resources.
Transparency	Regulatory systems should be transparent; requirements and decisions should be made known, and input should be sought on regulatory proposals.

ENABLERS OF GRP

Political & government support	• Sustained support at the highest political and government levels • Policy-makers, is essential for proper implementation of GRP. • strong political support
Good organization, governance & leadership	• Leadership is critical for setting and realizing the organizational vision, mission, policies and strategies, which in turn significantly contribute to organizational efficiency. • Organisational integrity
Effective communication, Collaboration& coordination	• Information exchange within & outside regulatory institution • Transparency and accountability • Avoid misleading the public • Collaboration of local international stakeholders
Robust and well functioning QMS	• systematic planning, control and improved quality in all processes in regulatory functio and ensures a comprehensive approach include risk management system
Sufficient and sustainable financial resources	Adequate financial resources to sustain the regulatory system Financial resource sustainable apart frm donations
Competent human resources	• Attract and retain competent Staff • Policies; training and development of careers
Preset organizational ethics & values	• Ethical principles , values and professionalism • Trained , code of conduct
Science & data driven regulatory decision-making process	• Scientific based and accurate data • Consistency & predictable outcome • Adherence to International standards

Implementation of GRP

- Consideration of the realities of individual legal and regulatory systems.
- Transparent, predictable processes should be used to ensure quality
- Regulatory oversight that achieves the intended objectives while minimizing negative impacts and costs.
- Regulatory systems should be sufficiently flexible for the processes to be applied proportionately
- Sustained support at the highest levels, with adequate resources, is essential.

SAHPRA
South African
Health Products
Regulatory Authority

Thank you

SAHPRA
South African
Health Products
Regulatory Authority