



Good regulatory practices in the regulation of medical products



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Background

The importance of robust regulatory systems was recognized by the **Sixty-Seventh World Health Assembly** when it endorsed resolution **WHA 67.20**, Regulatory system strengthening for medical products.

The resolution notes that “**effective regulatory systems** are an essential component of health system strengthening and contribute to better public health outcomes”, that “**regulators** are an **essential part** of the **health workforce**” and that “**inefficient regulatory** systems themselves can be a **barrier** to access to **safe, effective and quality medical products**”

Definition

- GRP can be defined as a set of **principles** and **practices** applied to the **development, implementation** and **review** of regulatory **instruments** – **laws, regulations** and **guidelines** – to achieve public health policy objectives in the most efficient way.
- GRP provide a means of establishing and implementing **sound, affordable, efficient regulation** of medical products as an important part of health system **performance** and **sustainability**.

Purpose

This document is also meant to **guide** Member States in prioritizing the functions of their regulatory system according to their **resources, national goals, public health policies, medical products policies and the medical product environment.**

This “**principles-based**” document will be supplemented by practical guides and tools to facilitate implementation of GRP by organizations responsible for the regulation of medical products.

This basic document is complemented by related guidance on best regulatory practices, including **Good Governance Practices, Good Reliance Practices, Good Review Practices** and **Quality Management Systems For National Regulatory Authorities.**

Scope

- This document presents **principles** and **considerations** in the development and use of the regulatory instruments that **underpin** regulatory activities.
- The document is also intended for a number of related audiences:
 - ✓ **institutions and policy-makers** responsible for formulating health policies, laws, regulations and guidelines;
 - ✓ **institutions that, together, form national or supranational systems** for regulation of medical products;
 - ✓ **regulatory networks** and parties affected by or otherwise interested in regulatory frameworks, such as industry or other developers of medical products

Objectives

Effective Regulations

Higher-Quality Regulation

Better Regulatory Decision Making

Compliance

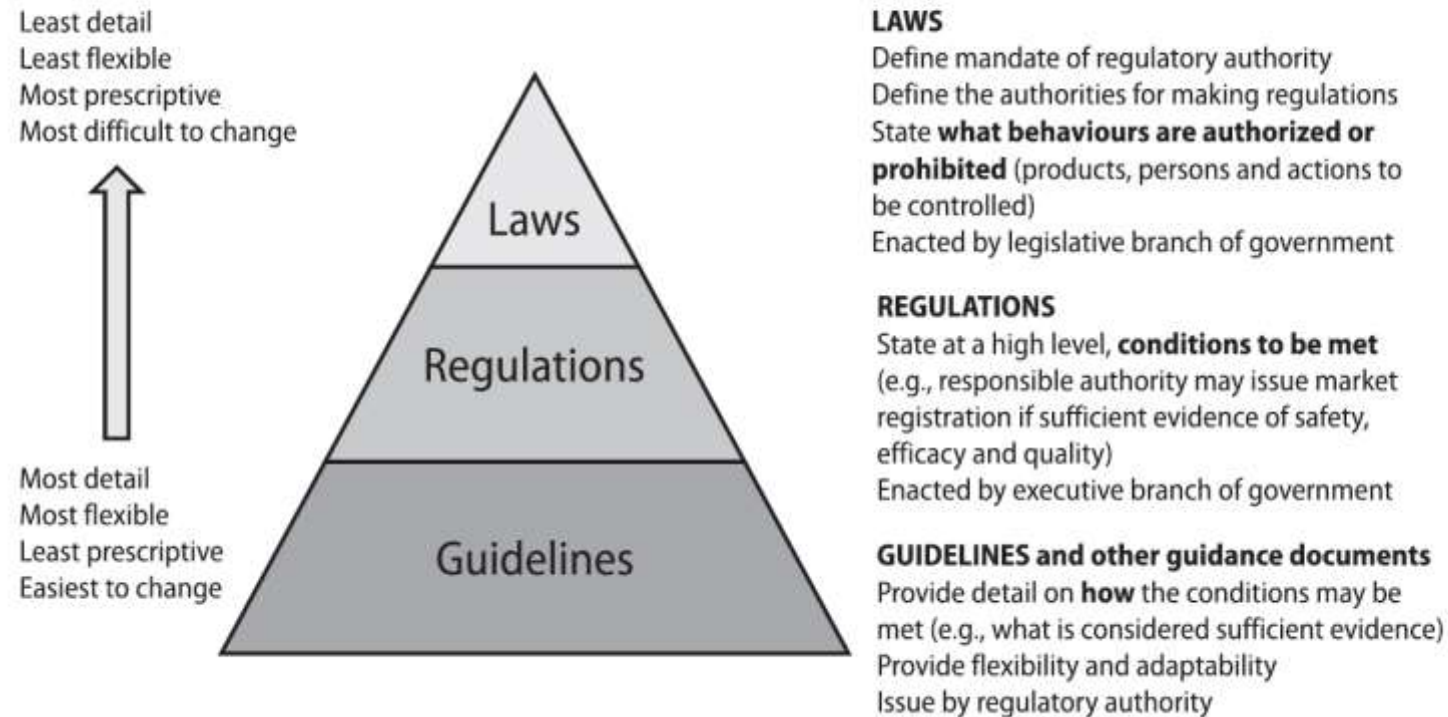
Better Public Health Outcomes

serve and protect public health and patients' interests, with respect for all applicable ethical principles



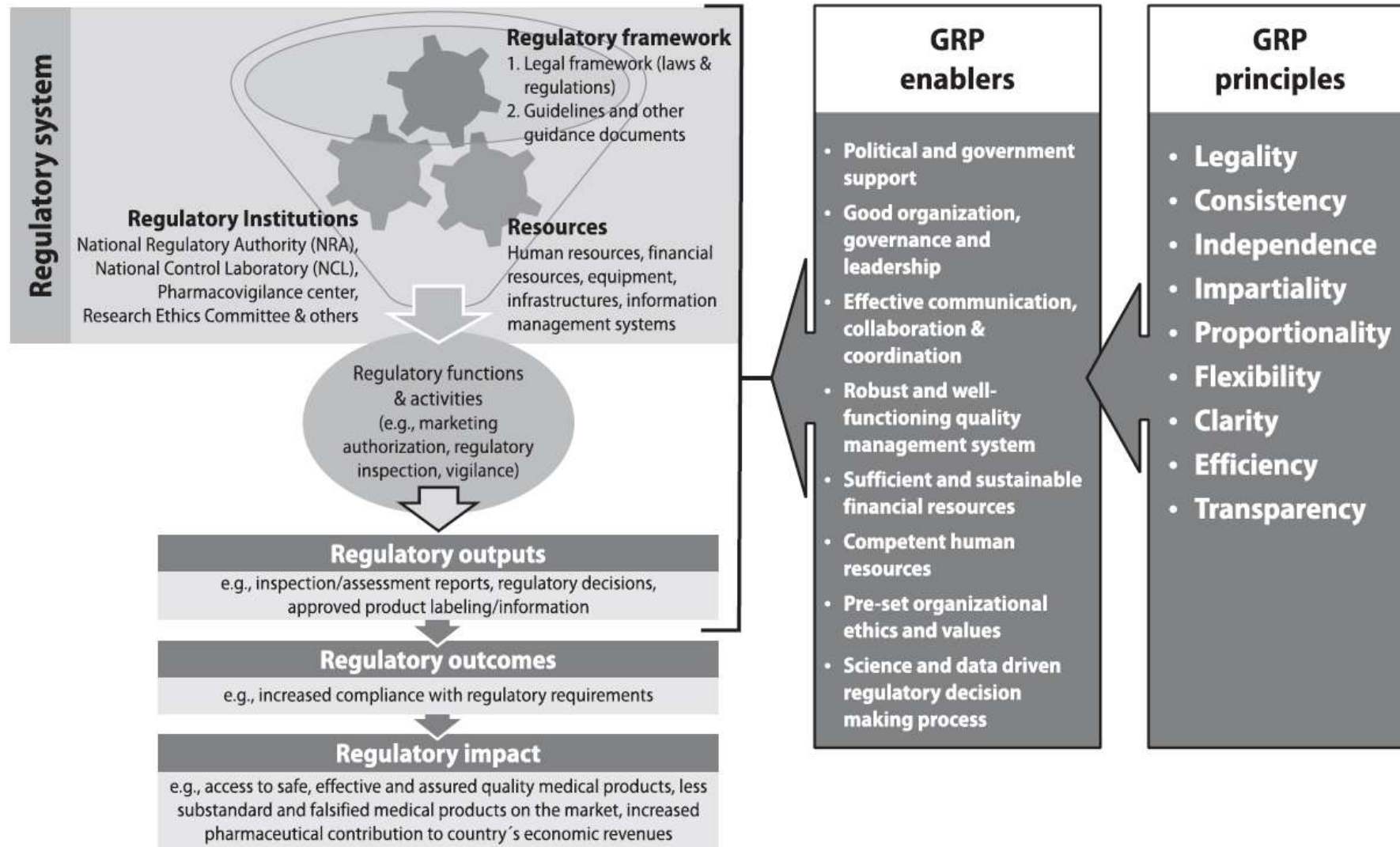
Overview of a regulatory system for medical products

- Architecture of a regulatory framework 279 Annex 11 7.2
Components of a regulatory system



Overview of a regulatory system for medical products

Principles and enablers of good regulatory practices (GRP) and components of a regulatory system



Principles of good regulatory practices

Legality

- Regulatory systems and the decisions that flow from them must have a sound **legal basis**.

Consistency

- Regulatory oversight of medical 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.

Principles of good regulatory practices...Cont

Flexibility

- Regulatory oversight should **not be prescriptive** but rather **be flexible** in responding to a changing environment and unforeseen circumstances.

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**.

Transparency

- Regulatory systems should be **transparent**; **requirements** and **decisions** should be made known, and input should be sought on regulatory proposals.

Enablers of good regulatory practices

Political and government-wide support

- Sustained support at the highest political and government levels, including policy-makers, is essential for proper implementation of the concept and principles of GRP

Effective organization and good governance supported by leadership

- The structure and line of authority among and within all institutions in the regulatory system should be well defined
- If more than one institution is involved in the regulatory system, the legislation or institutional regulation should provide for clear coordination and no overlap of regulatory activities.

Inter- and intra-organizational communication, collaboration and coordination

- Adequate, effective communication plays a fundamental role in the exchange of information within and outside the institutions that form the regulatory system.
- When regulatory authorities communicate regularly, both internally and externally, they remain more transparent and accountable.
- Communication of correct information prevents potential misunderstandings and dissemination of misleading information to patients and the public

A robust, well-functioning quality management system

- Sustained support at the highest political and government levels, including policy-makers, is essential for proper implementation of the concept and principles of GRP

Enablers of good regulatory practices....Cont

Sufficient, sustainable financial resources

- **Adequate financial resources** to fulfil its regulatory mandate effectively and to **improve** the **performance** of regulatory activities continuously are essential.
- The financial resources of all institutions of the regulatory system **should be sustainable**, apart from donations from donors or philanthropic entities.

Competent human resources

- The structure and line of authority **among and within all institutions** in the regulatory system **should be well defined**

Organizational ethics and values

- Regulatory personnel should abide by **organizational ethical principles and values** and show professionalism.
- All regulatory staff should **be made aware** of and be trained in the **ethical principles and values** of the regulatory authority (e.g. a code of conduct).

Science- and data-driven decision-making process

- Regulatory decisions and decision-making **should be based on scientific foundations** and **accurate data** rather than intuition or arbitrariness.
- Science based decisions provide for **consistent, predictable regulatory outcomes**.

Implementing good regulatory practices

- **WHO Member States** are encouraged to implement GRP in their regulatory systems.
- **Transparent, predictable processes** should be used to ensure **high-quality regulatory** oversight that achieves the intended objectives while **minimizing negative impacts and costs**.
- Sustained support at the **highest levels**, with adequate resources, is essential.



Acknowledgments

Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India, CDSCO

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Thank You