Importance of Predictability and Transparency to Facilitate Reliance Scheme

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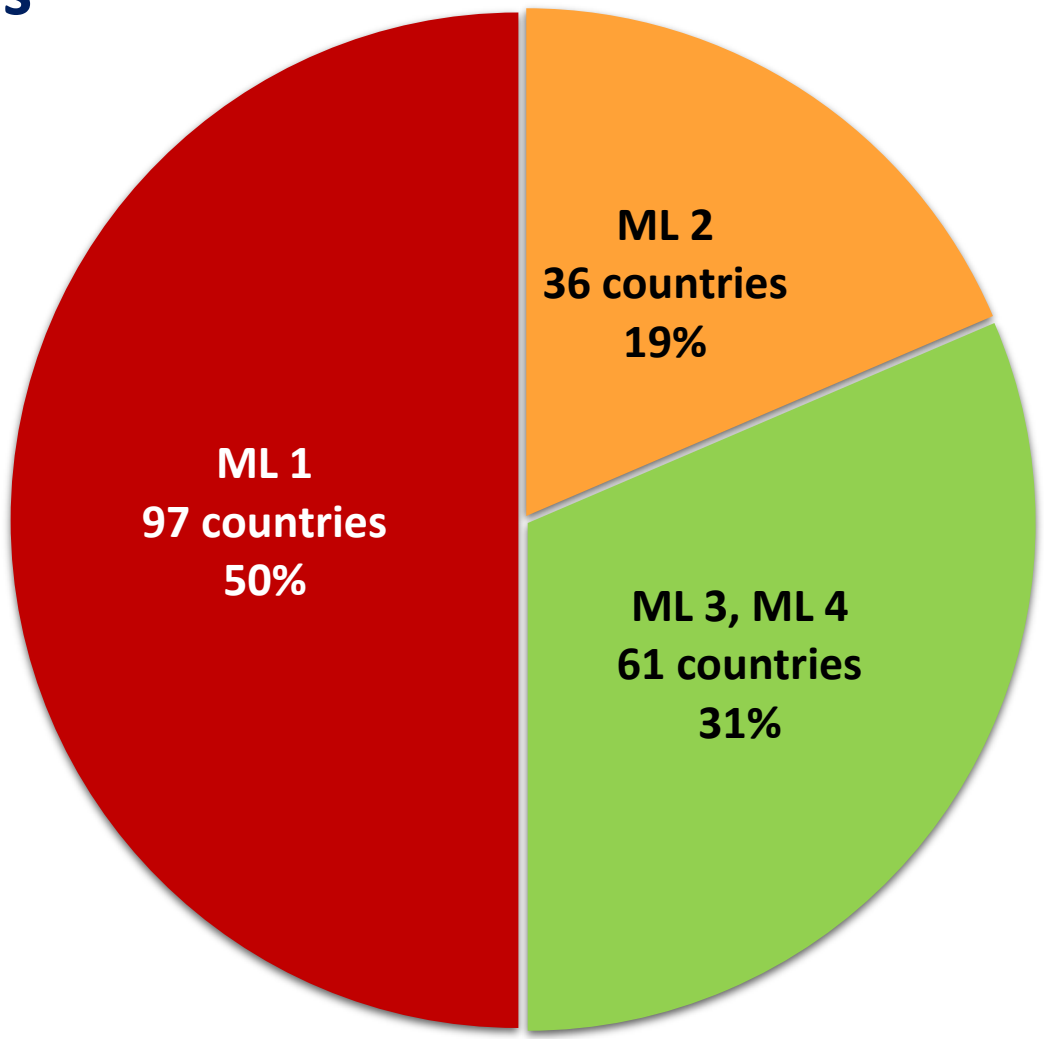
WHO

Overall regulatory systems' maturity level of WHO Member States and major challenges

Objectives of WHO Regulatory Systems Strengthening

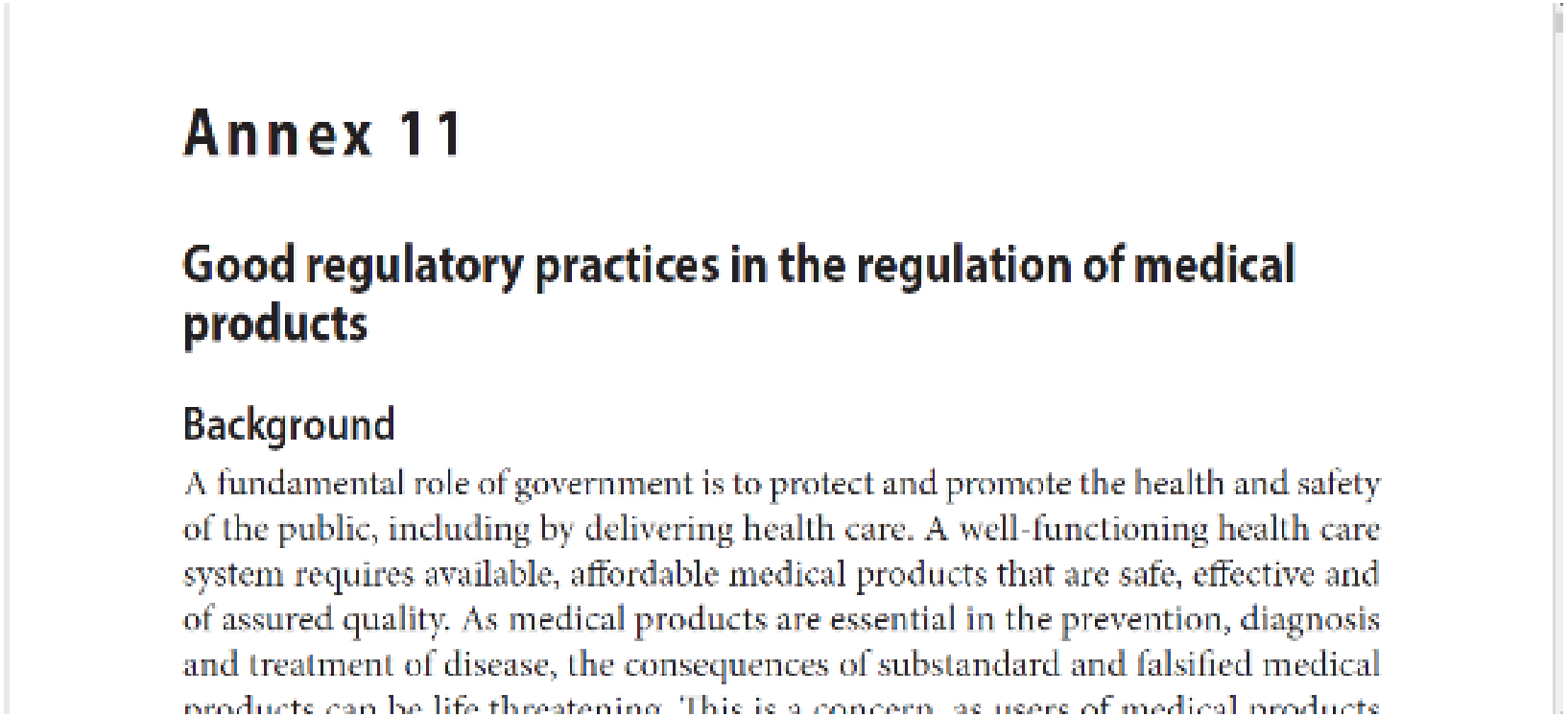
- *Build capacity in Member States consistent with good regulatory practices*
- *Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance*

- **Resolution WHA 67.20 in 2014**
  - ✓ Recognized the importance of strong regulatory systems to a well-functioning healthcare system and the attainment of health-related SDGs and UHC



WHO Good Regulatory Practices Guideline

55th report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSPP)



Annex 11

Good regulatory practices in the regulation of medical products

Background

A fundamental role of government is to protect and promote the health and safety of the public, including by delivering health care. A well-functioning health care system requires available, affordable medical products that are safe, effective and of assured quality. As medical products are essential in the prevention, diagnosis and treatment of disease, the consequences of substandard and falsified medical products can be life threatening. This is a concern, as users of medical products

Link: Annex 11: Good regulatory practices in the regulation of medical products

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Nine high-level GRP principles

Legality	Consistency	Independence
Impartiality	Proportionality	Flexibility
Clarity	Efficiency	Transparency

Enablers for Good Regulatory Practices (1/2)

1. **Political and government-wide support**: Sustained support at the highest political and government levels, including policy makers, is essential for the proper implementation of the concept and principles of GRP.

2. **Effective organization and good governance supported with leadership:** Leadership is critical for setting and carrying out the organizational vision, mission, policies and strategies which in turn significantly contribute to organizational efficiency.

3. **Inter-and-intra-organizational communication, collaboration and coordination:** Adequate and effective communication plays a fundamental role for exchanging information within and outside the institutions forming the regulatory system. When regularly communicating both internally and externally, regulatory authorities remain more transparent and accountable.

4. **A robust and well-functioning quality management system**: which includes the application of quality risk management (QRM) principles, is a valuable tool that helps regulatory authorities to achieve greater credibility for their decisions, and greater stability and consistency in their operations

Enablers for Good Regulatory Practices (2/2)

5. Sufficient and sustainable financial resources: Investment in regulatory systems is critical to a well-functioning health care system. Securing financial resources to effectively carry out the regulatory mandate and to continuously improve the performance of regulatory activities is an essential enabler for regulatory system independence, impartiality, consistency and efficiency.

6. Competent human resources: An array of technical and scientific knowledge and the skills of regulatory staff contribute to the development, implementation and maintenance of a regulatory system for medical products. Personal and career development policies and measures are critical for regulatory authorities to attract and recruit competent staff and, in addition, to retain competent staff in the service.

7. Pre-set organizational ethics and values: Regulatory personnel should abide by ethical principles, organizational values, and professionalism (e.g. Code of conduct).

8. Science- and data-driven decision-making process: Regulatory decisions, along with their making process, should be based on scientific foundations and accurate data rather than intuitions or arbitrariness. Adherence to international standards and guidelines represent key enablers to science-based regulatory decision-making.

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Six High-Level GRelP principles

Universality

Applies to all NRAs irrespective of their levels of maturity or resources

Sovereignty of decision-making

NRAs maintain independence, sovereignty and accountability

Transparency

Key enabler to adopting new, more efficient ways of conducting regulatory operations. NRAs to be transparent about their reliance approaches

Respect of national/regional legal basis

Coherent with national/regional frameworks and policies

Consistency

Established for specific and well-defined categories of products and processes

Competency

Build and maintain appropriate competencies and scientific expertise

GRP main principles

Consistency

Regulatory oversight of medical products should be consistent with existing government policies and legislation and be applied in a consistent and predictable manner

Key elements:

- Fit coherently into the national legal and policy framework
- Complementary and not conflicting
- Consistent implementation and enforcement

GBT:

MA04.04: The same criteria apply for assessing applications regardless of the origin of or destination for the medical products (e.g., domestic, foreign, public sector, or private sector)

RS01.04: All regulatory entities (central and decentralized ones) follow non- contradictory regulations, standards, guidelines and procedures.

MA01.10: There are guidelines on the format and content for submission of MA applications that are consistent with the WHO or other internationally accepted standards

GRP main principles

Transparency

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

Key elements:

- Investment and a culture of openness, supported by government policy, commitment and action
- Stakeholders should be consulted
- Access to regulations and decisions
- disclosure should be consistent with national laws on access to information.

GBT:

RS01.06: Legal provisions and regulations define requirements of transparency and dissemination of information to the public and relevant stakeholders.

RS09.04: Information on marketed medical products, authorized companies and licensed facilities is publicly available.

MA05.02: Updated list of all medical products granted MA is regularly published and publicly available

RS09.04: Information on marketed medical products, authorized companies and licensed facilities is publicly available.

GRP main principles

Efficiency

Regulatory systems should achieve the intended results within the required time and at reasonable effort and cost

Key elements:

- Achieve the public health goals
- Effective use of resources and information from other authorities
- Most efficient and least burdensome means of achieving regulatory purposes
- Evaluation of the total burden and resources
- Explore ways of improving efficiency
- Alignment of regulatory requirements
- Contribution of regulated entities
- Performance-based indicators

GBT:

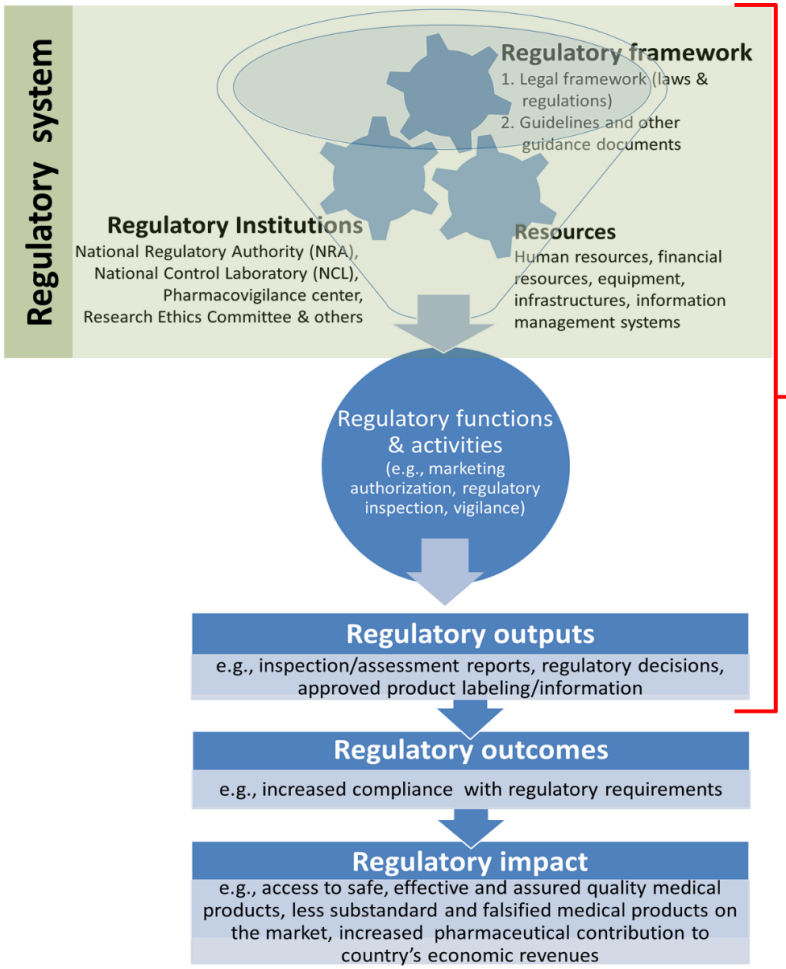
MA04.06: Timelines for the assessment of the applications are defined and an internal tracking system has been established to monitor adherence to the targeted time frames

MA01.08: Legal provisions or regulations allow the NRA to recognize and/or rely on MA-relevant decisions, reports or information from other NRAs or regional and international bodies

MA06.02: Performance indicators for registration and MA activities are established and implemented

International collaboration

Principles and Enablers of GRP
Components of a Regulatory System



GRP enablers

- Political and government support
- Good organization, governance and leadership
- Effective communication, collaboration & coordination
- Robust and well-functioning quality management system
- Sufficient and sustainable financial resources
- Competent human resources
- Pre-set organizational ethics and values
- Science and data driven regulatory decision making process

GRP principles

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

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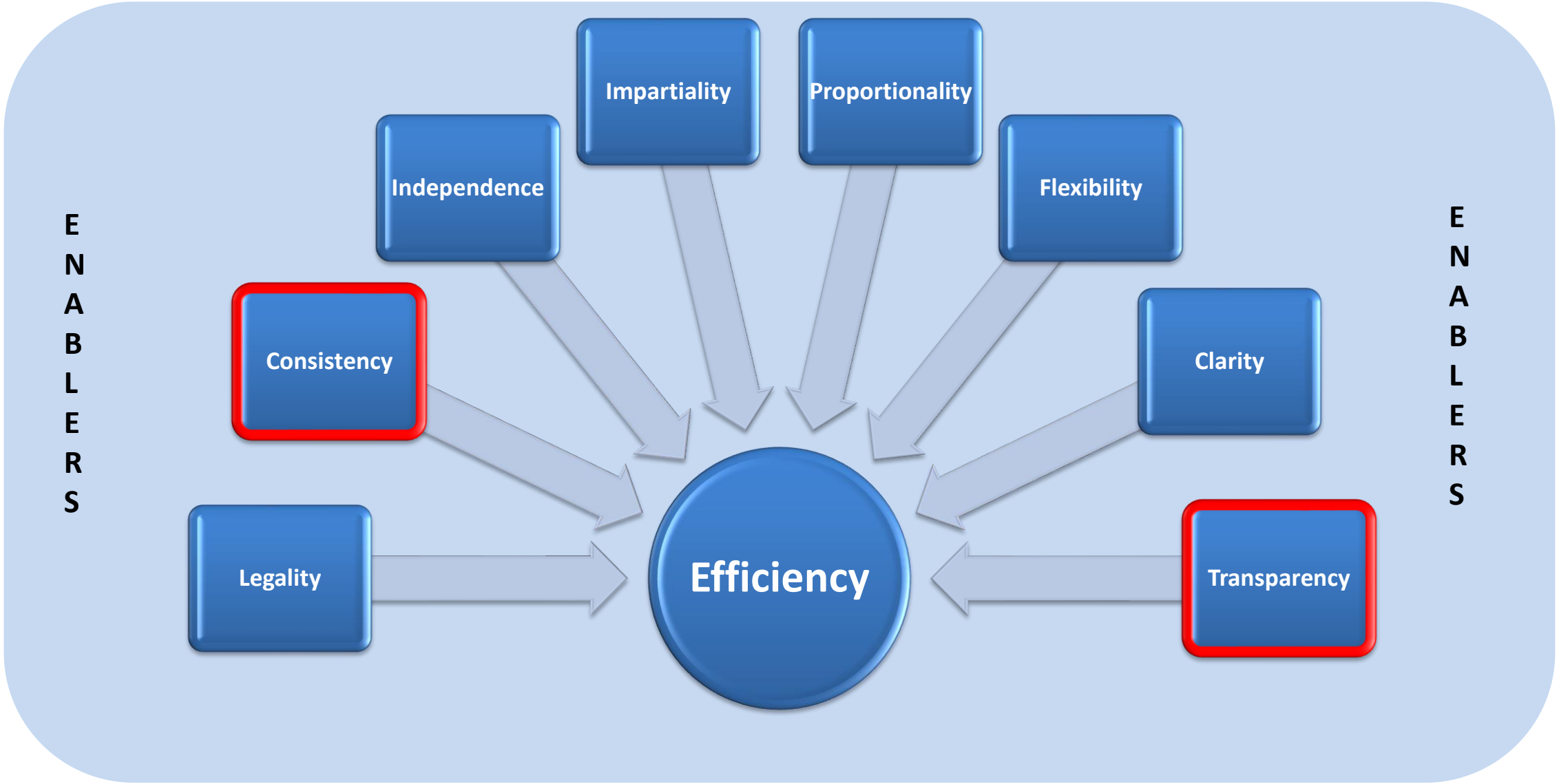

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Thank you

For more information, please go to our website:

https://www.who.int/teams/regulation-prequalification/regulation-and-safety/rss

Or contact: nra_admin@who.int

Regulatory Systems Strengthening [RSS] Team
Regulation and Safety [REG] Unit
Regulation and Prequalification [RPQ] Department
Access to Medicines and Health Products [MHP] Division