Reliance and Good Regulatory Practices

Smart regulation a risk based approach

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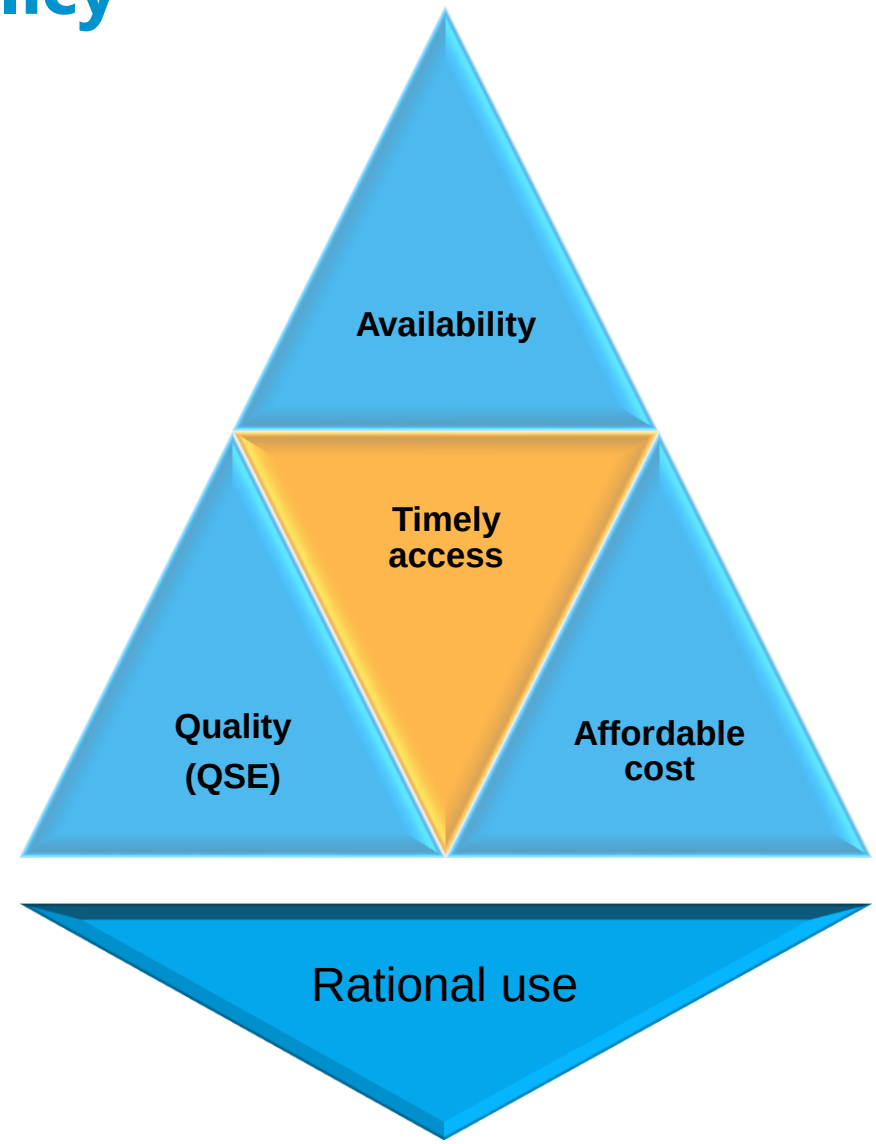
National Medicine Policy

Key components of a National Medicine Policy



At issue

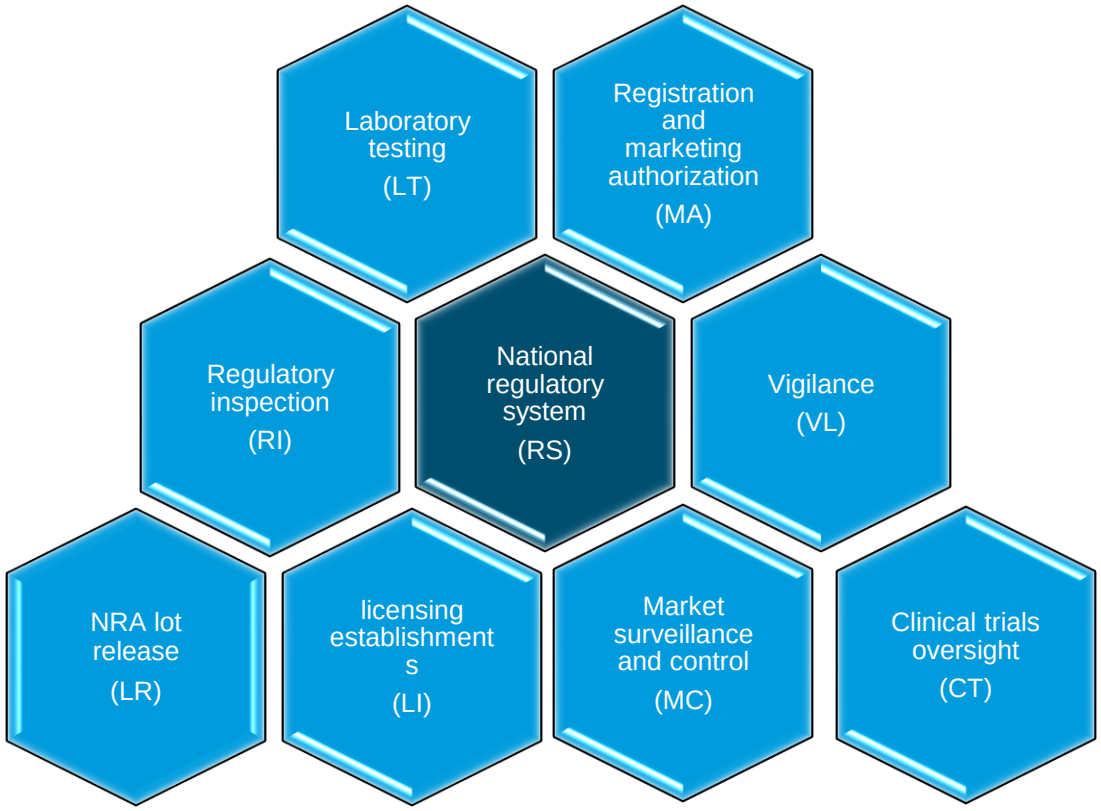
- Regulatory authorities under mounting pressure to improve performance and facilitate timely access to safe, effective and quality medical products

- Task has become more challenging due to globalization, increasingly complex technologies and growing public expectations

- No where are these challenges more acute than in low and middle income countries (LMICs)

Reliance and recognition

Promoting reliance and recognition accross regulatory functions



Definitions

Reliance:

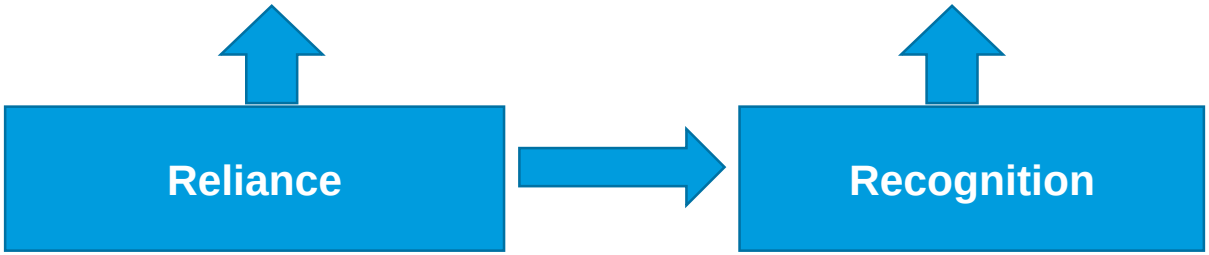
act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision.

Recognition:

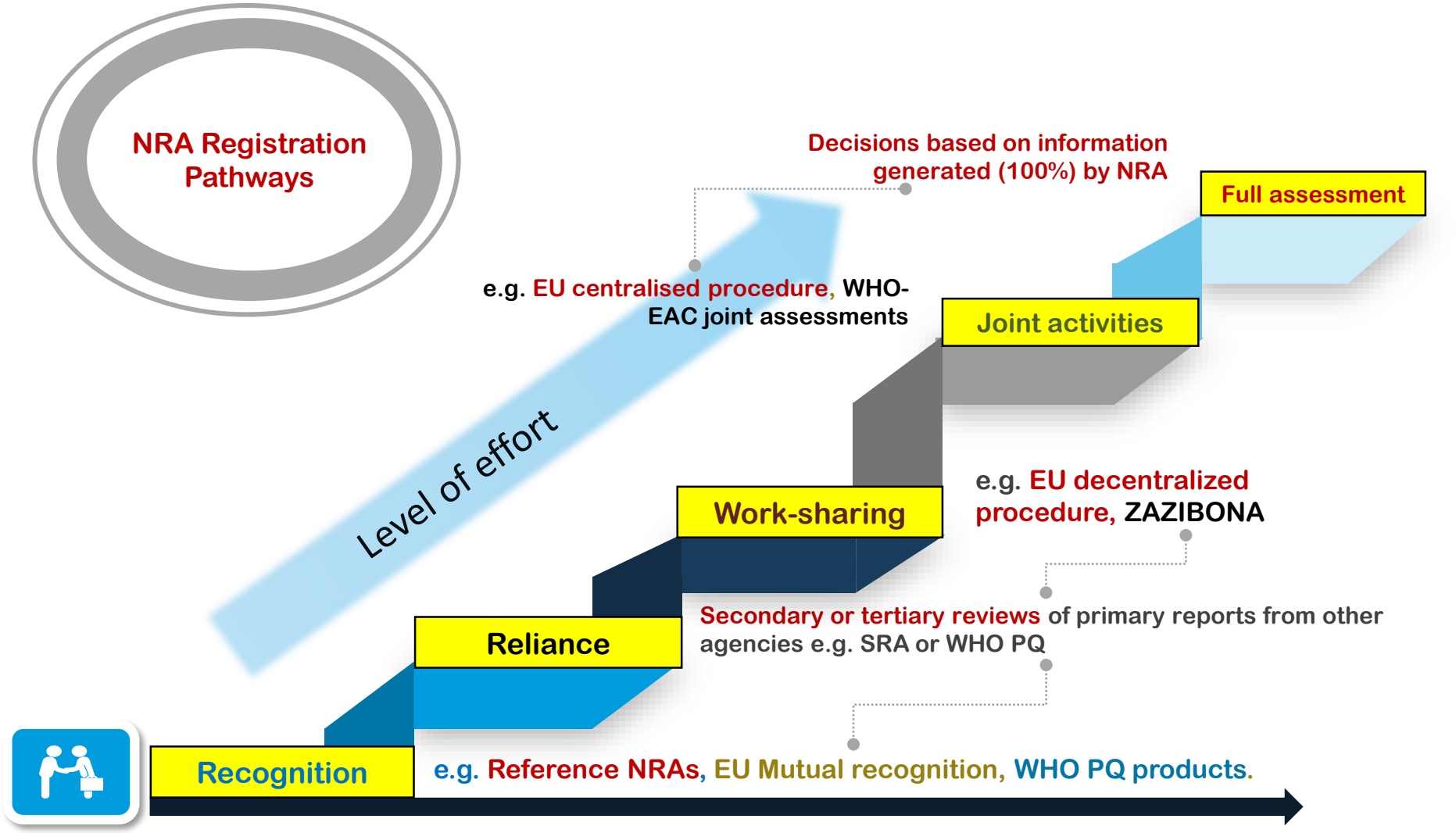
the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B.

Reduction:
streamline/reduce internal work

Replacement:
operationally, rely on decisions



- Both terms reflect concept of ‘relying on’ or ‘taking account of’ the output of other agencies
- May be unilateral or mutual
- May also be part of step-wise approach (confidence building) leading to recognition
- Sovereignty maintained in both cases



NRA capabilities

Promoting reliance and recognition through regulatory functions

RS03.04: Documented policies, procedures and mechanisms, including written criteria, are established for recognition and reliance on decisions of other NRAs (if applicable).

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

RI01.05: Legal provisions and regulations allow the recognition of and/or reliance on foreign NRA inspections and enforcement actions based on well- defined criteria.

LT01.02: Legal provisions and regulations allow the NRA to recognize and use laboratory testing-related decisions, reports or information from other NRAs or regional and international bodies.

CT01.11: Legal provisions or regulations allow the NRA to recognize and use relevant CT decisions, reports or information from other NRAs or from regional and international bodies.

LR01.02: Acceptance policy and criteria for lot release performed by another NRA are documented.

GOOD REGULATORY PRACTICES and GBT

GRP Part 1: Principles of GRP

World Health Organization

Legality	**Impartiality**	**Consistency**
Proportionality	**Flexibility**	**Effectiveness**
Efficiency	**Clarity**	**Transparency**

Main themes of GBT and GRP

World Health Organization

GRP Principles

1. Legality
2. Impartiality
3. Consistency
4. Proportionality
5. Flexibility
6. Effectiveness
7. Efficiency
8. Clarity
9. Transparency

GBT Indicators

1. Legal provisions, regulations and guidelines
2. Organization and governance
3. Policy and strategic planning
4. Leadership and crisis management
5. Transparency, accountability and communication
6. Quality and risk management system
7. Regulatory process
8. Resources (HR, FR, Experts, Infrastructure, Equipment and IMS)
9. Monitoring progress and assessing impact

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Principles of good regulatory practices
LEGALITY

World Health Organization

GRP

Legality:

Regulation should have a sound legal basis and should be consistent with existing legislation, including international norms or agreements.

GBT

RS01.01: Legal provision and/or regulation define the medical products that should be regulated.

RS01.02: Legal provision and/or regulation define the institutions involved as part of the regulatory system; their mandate, functions, roles, responsibilities and enforcement power.

MC01.02: Legal provisions and/or regulations entail market surveillance and control activities which include product sampling from different points of the supply chain.

LI01.02: There are legal provisions to empower the NRA to issue, suspend or revoke licenses for establishments.

Principles of good regulatory practices
IMPARTIALITY

World Health Organization

GRP

Impartiality: Regulation and regulatory decisions should be impartial in order to be fair and to avoid conflicts of interest, unfounded bias or improper influence from stakeholders.

GBT

RS01.08: The NRA consults or involves specific sectors of the civil society (such as NGOs representing health professionals, the industry, consumers and patients) during the development or adoption of regulations and guidelines.

RS02.04: Independence of NRA from researchers, manufacturers, distributors and wholesalers, as well as the procurement system.

RS06.04: Documented mechanism to handle potential conflicts of interest of internal or external experts and committee members, to gather declarations of interest and guarantee the update of these declarations for all regulatory functions.

Principles of good regulatory practices
CONSISTENCY

World Health Organization

GRP

Consistency: Regulations should be clear and predictable; both the regulator and the regulated party should understand the behavior and the conduct that are expected and the consequences of noncompliance.

GBT

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

RS01.08: Development of the regulations involves the national regulatory authority (NRA) responsible for their implementation and enforcement.

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

RI04.06: The same criteria are used for the inspection of domestic, public and private facilities regardless the ownership.

Principles of good regulatory practices
PROPORTIONALITY

World Health Organization

GRP

Proportionality: Regulations and regulatory decisions should be proportional to the risk and should not exceed what is necessary to achieve the objectives.

GBT

RS05.08: External and internal issues including relevant potential risks are defined and assessed periodically for proper risk mitigation.

RS04.05: Written criteria to cover circumstances in which the routine regulatory processes may not have to be followed in relation to crises and emergencies linked to a risk management plan.

RI04.03: Plan for inspections based on quality risk management is in place.

RI04.05: Inspection findings/observations are categorized according to quality risk management.

LT03.01: Documented and implemented policy for testing exists that is based on the product's risk.

Principles of good regulatory practices
FLEXIBILITY

World Health Organization

GRP

Flexibility: Regulations should not be prescriptive; they should allow flexibility in responding to a changing regulated environment and different or unforeseen circumstances.

GBT

RS04.05: Written criteria to cover circumstances in which the routine regulatory processes may not have to be followed in relation to crises and emergencies linked to a risk management plan.

MA01.06: There are legal provisions to cover circumstances in which the routine MA procedures may not be followed (e.g. for public- health interests).

MA01.07: Legal provisions and/or regulations allow the NRA to recognize and/or use MA-relevant decisions, reports or information from other NRAs or regional and international bodies.

MA04.07: There are documented mechanisms to handle non routine registration and marketing authorization requirements in special situations (e.g. public-health interest).

Principles of good regulatory practices
EFFECTIVENESS and EFFICIENCY

World Health Organization

GRP

Effectiveness: Regulations should produce the intended result.

Efficiency: Regulations should achieve their goals within the required time, effort and cost.

GBT

RS10.01: Requirements established to monitor, supervise and review the performance of the NRA and affiliated institutions using key performance indicators.

MA04.06: There are timelines for the assessment of the applications and an internal tracking system is established to follow the targeted time frames.

MA04.10: The regulations and/or guidelines for good review practices (GRevP) are developed or recognized and implemented.

MA06.02: Performance indicators for registration and/ or market authorization activities are established and implemented.

LT08.04: Performance indicators for laboratory testing activities are established.

Principles of good regulatory practices
CLARITY

World Health Organization

GRP

Clarity: Regulations should be accessible to, and understood by, the users.

GBT

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

RS01.08: The NRA consults or involves specific sectors of the civil society (such as NGOs representing health professionals, the industry, consumers and patients) during the development or adoption of regulations and guidelines.

RS01.09: A guideline on complaints and appeals against regulatory decisions is available to the public.

RS04.01: Leadership ensures that the strategic priorities and objectives are well known and communicated throughout the NRA.

RS09.02: The information on laws, regulations guidelines and procedures is publicly available and is kept duly updated.

Principles of good regulatory practices
TRASPARENCY

World Health Organization

GRP

Transparency: Regulatory systems should be transparent; requirements and decisions should be made known to affected parties and, where appropriate, to the public in general.

GBT

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

RS09.03: Information on decisions related to regulatory activities are available to the public.

RS09.09: The NRA has its own web page with timely information that gives public access to related legal provisions, guidelines and decisions.

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

RI06.02: The updated list/database of all inspected facilities along their regulatory decisions, actions and enforcement is regularly published and publicly.

RI06.03: Inspection metrics are regularly published and publicly available.

GRP Part 2. Implementing good regulatory practices

2.1 Policy-making process and regulatory impact analysis (RIA)

2.2 Compliance and enforcement

2.3 Regulatory consultation

2.4 A forward-looking regulatory agenda

2.5 Monitoring and evaluation

2.6 Management of the regulatory stock

Smart regulation an avenue for

the NRAs to reduce regulatory burden and duplication

promote efficient use of resources by re-allocating resources to high-risk areas/products

Thank you

World Health Organization

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Regulatory Systems Strengthening (RSS)

Regulation of Medicines and Other Health Technologies (RHT)

World Health Organization (Geneva, Switzerland)

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