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Session 5: Collaborative Approaches and Reliance Procedures

Update from WHO: Global Perspective on Regulatory Reliance

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Access to medical products – global challenge

- Good health is impossible without access to medical products;
- Today, approximately half of the world's population is **unable to access essential medicines**;
- Reasons for limited/insufficient access are numerous – including:
  - Financial Barriers,
  - Intellectual Property Rights and Patents
  - Infrastructure and Distribution Challenges,
  - Limited Healthcare Workforce,
  - Supply Chain Issues,
  - Insufficient/inadequate regulatory capacity and lack of collaboration and work sharing between countries in regulation of medical products.

WHO efforts to facilitate good quality decisions – based on reliance

Medical products should be used in the countries only after approval by the national or regional regulatory authority - in line with current international standards (WHA Resolutions: WHA 67.20 (2014); WHA 67.21 (2014); WHA63.12 (2010)

- Strong regulatory capacity is an essential component of a well-functioning healthcare system (Resolution WHA 67.20, 2014);
- Globally, **>70% of countries** have weak national regulatory systems;
- Only **57 countries** (30%) have regulatory systems at GBT maturity level 3 or 4 (https://www.who.int/initiatives/who-listed-authority-reg-authorities);
- WHO regulatory systems strengthening programme responds to addressing this challenge:
  - Benchmarking to document strengths and identify gaps;
  - Capacity building, including training based on Global Competency Framework and Regulatory Curriculum;
  - **Promoting smart regulation – good regulatory and reliance practices.**

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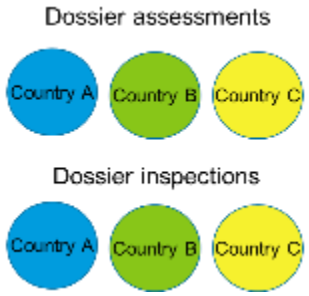
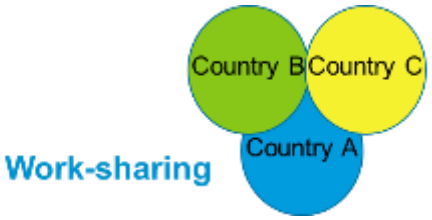
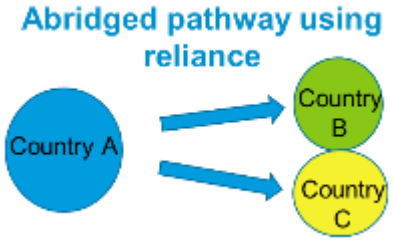
Options to facilitate good quality regulatory decisions – reliance in the focus



Standard processes

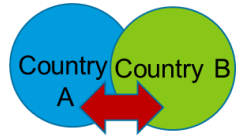




Work-sharing, including joint activities
Abridged pathways using **reliance**

Recognition

Unilateral



Mutual recognition

Independent decisions
based on its own reviews and/or inspections

Leveraging regulatory work
Performed by other competent and trusted authorities to reduce the workload

Unilateral or mutual recognition
based on treaties or equivalent

Building trust between NRAs, increasing reliance and efficiency

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Promoting Good Regulatory and Reliance Practices

Good regulatory practices

Set of principles and practices applied to the development, implementation and review of regulatory instruments in order to achieve a public health policy objectives in the most efficient way

Addressing responses to **common gaps in regulatory practices** identified during benchmarking of national regulatory systems

Relevant to all regulators, irrespective of resources, maturity or regulatory models (national, supranational and multiple institutions)

Annex 11: Good regulatory practices in the regulation of medical products (March 2021)

Good reliance practices

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision.

Importance of **international cooperation** to ensure the safety, quality and efficacy or performance of locally used medical products

Make best use of available resources and expertise, avoid duplication and concentrate regulatory efforts and resources where most needed

Annex 10: Good reliance practices in the regulation of medical products (March 2021)

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Reliance to support national regulatory decisions

- Promoting a more efficient approach to regulatory oversight, thereby improving access to quality-assured, effective and safe medical products over their entire life-cycle;
- Relying authority remains **independent, responsible and accountable** regarding the decisions taken, even when it relies on the decisions, assessments and information of others.

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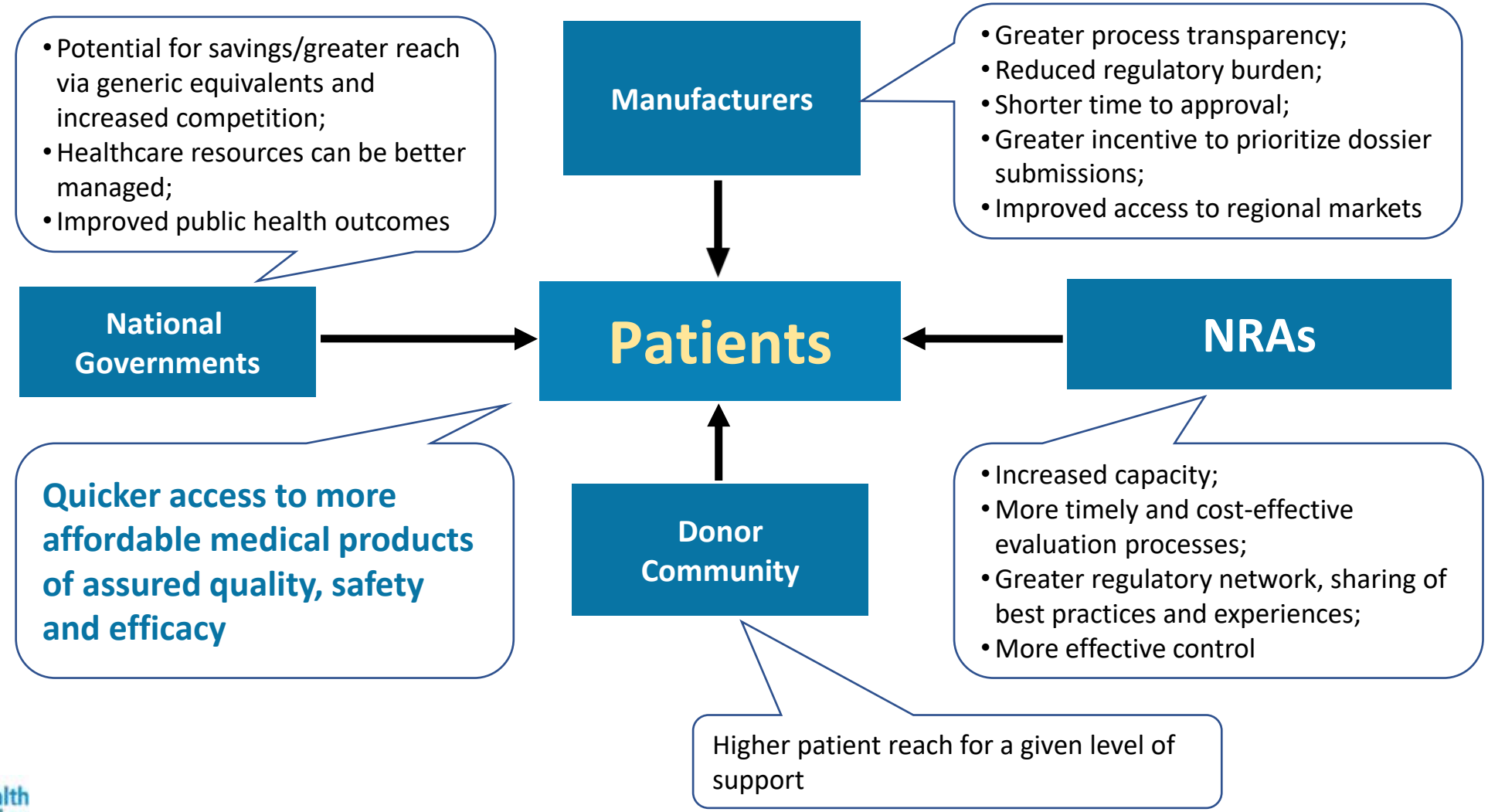
Patient-centric approach based on reliance is “CENTRAL” in the regulation of medical products



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Reliance is “implanted” in facilitated regulatory pathways

WHO PQ collaborative registration procedure

- Vaccines: 2004
- Medicines: Started in 2012
- FDA-WHO joint pilot to accelerate access to HIV medicines (CRP-lite)
- In Vitro Diagnostics: Pilot started in 2019, now operational
- Vector control: Pilot 2020

“SRA” collaborative registration procedure

- Initiated in 2015
- European Medicines Agency (EMA)
- UK Medicines and Healthcare Products Regulatory Agency (MHRA)
- 20 African NRAs

Regional regulatory harmonization initiatives and networks

African Medicines Regulatory Harmonization Initiative (AMRH)

ASEAN SIAHR Project

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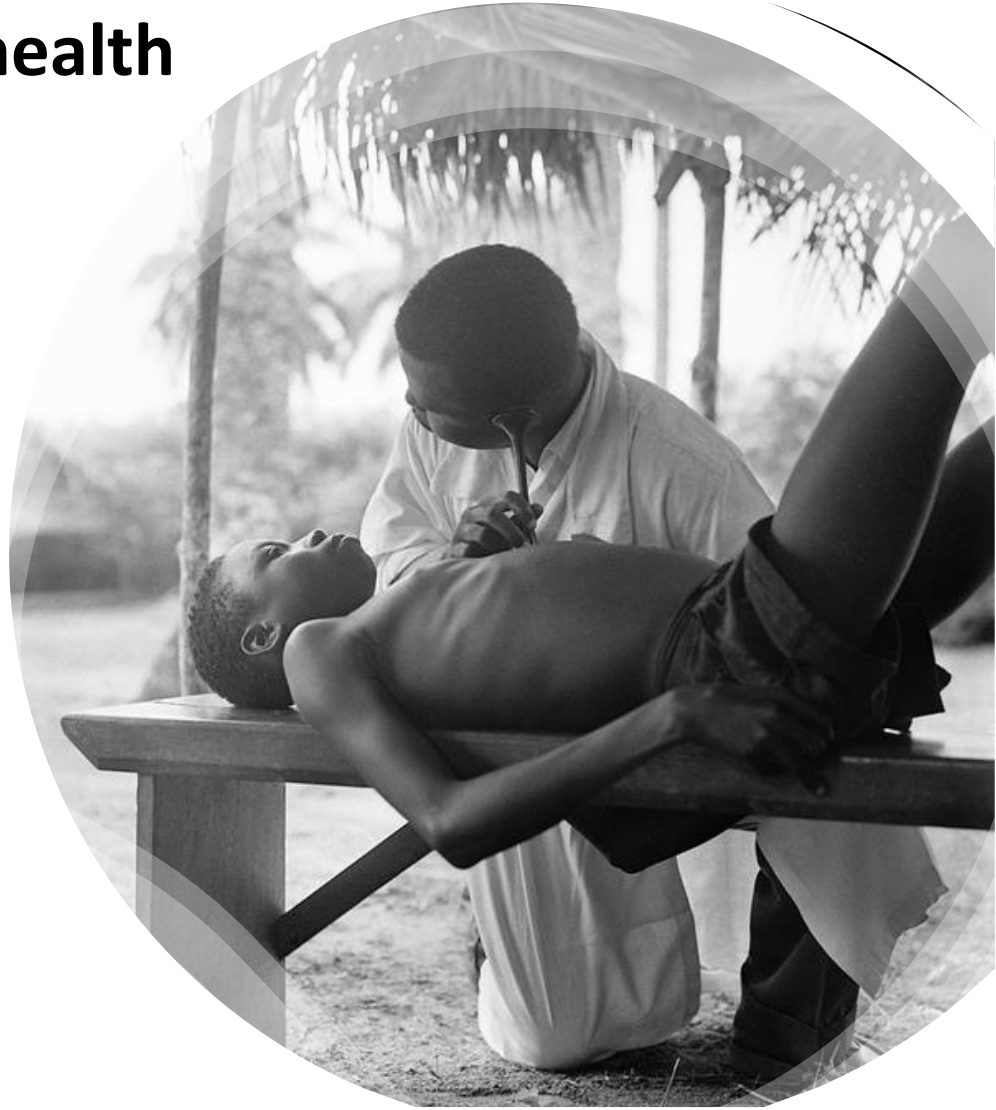
Call to action - join forces to build a harmonized regulatory framework that promotes global health

- Timely access to medical products – never-ending challenge;
- International regulatory collaboration, harmonization, and convergence **have no alternative** in ensuring the safety, efficacy, and quality of medical products globally;
- Overall, the reliance-based facilitated regulatory pathways underscore the critical importance of **joining forces among WHO, NRAs, industry, and procurers**;
- By embracing **collaboration, networking and applying reliance** we can accelerate access to medical products, enhance regulatory convergence, and strengthen global health resilience, ultimately improving the lives of people around the world.



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www.who.int/medicines

Thank you for your attention!

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