CMC STRATEGY FORUM
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Update From WHO: Global Perspective on Regulatory Harmonization and Convergence to Support Reliance.

Dr Samvel Azatyan
Team Lead, Regulatory Convergence and Networks
Regulation and Safety Unit, Regulation and Prequalification Department
World Health Organization

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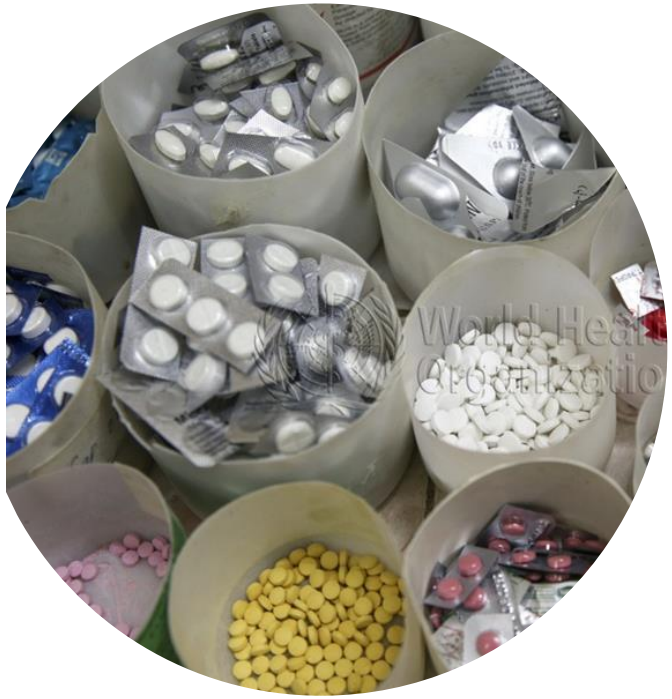
Access to essential medicines - part of the right to health

- 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.

Empowering Global Health: WHO's Initiatives to Strengthen Regulatory Systems in Member States

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 **59 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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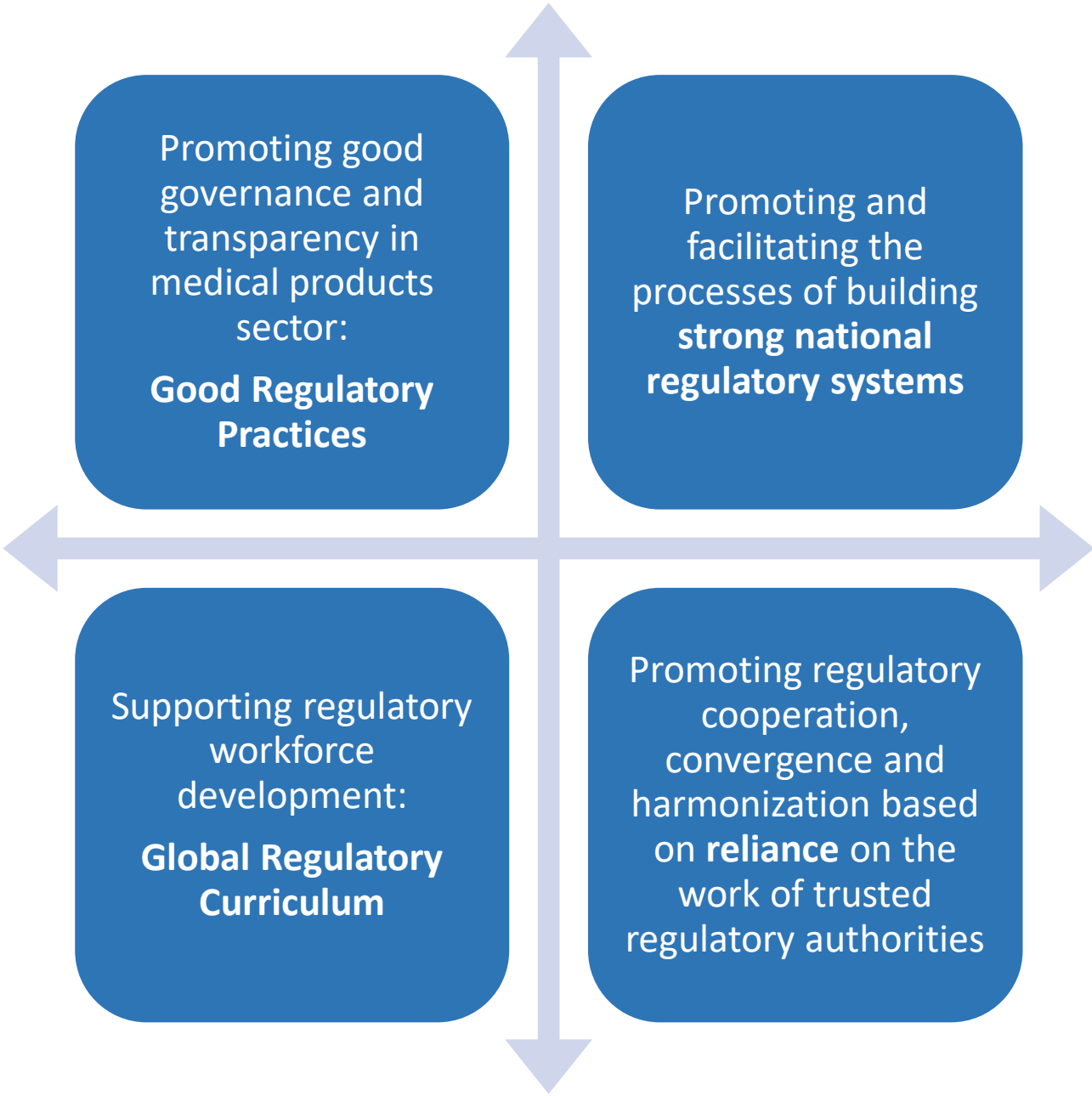
WHO endeavors to enhance the quality of national regulatory decisions by promoting reliance



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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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WHO Good Reliance Practices: Scope

- Encompasses reliance activities related to the regulation of medical products, including medicines, vaccines, blood and blood products, and medical devices (including in vitro diagnostics);
- Addresses all regulatory functions outlined in the WHO Global Benchmarking Tool, including registration and marketing authorization, vigilance, market surveillance and control, licensing of establishments, regulatory inspection, laboratory testing, oversight of clinical trials, and NRA lot release;
- The scope of coverage spans the entire life cycle of a medical product.

The high-level document will be complemented in a second step by a repository of case studies, practice guides and examples of practical applications of GReIP

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Reliance is “implanted” in facilitated regulatory pathways

WHO PQ collaborative registration procedure

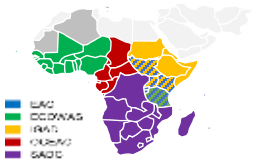
- Vaccines: 2004
- Medicines: Started in 2012
- FDA-WHO joint pilot to accelerate access to HIV medicines (CRP-lite)
- In Vitro Diagnostics: 2019
- Vector control: Pilot 2023

“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

Caribbean Public Health Agency CARPHA

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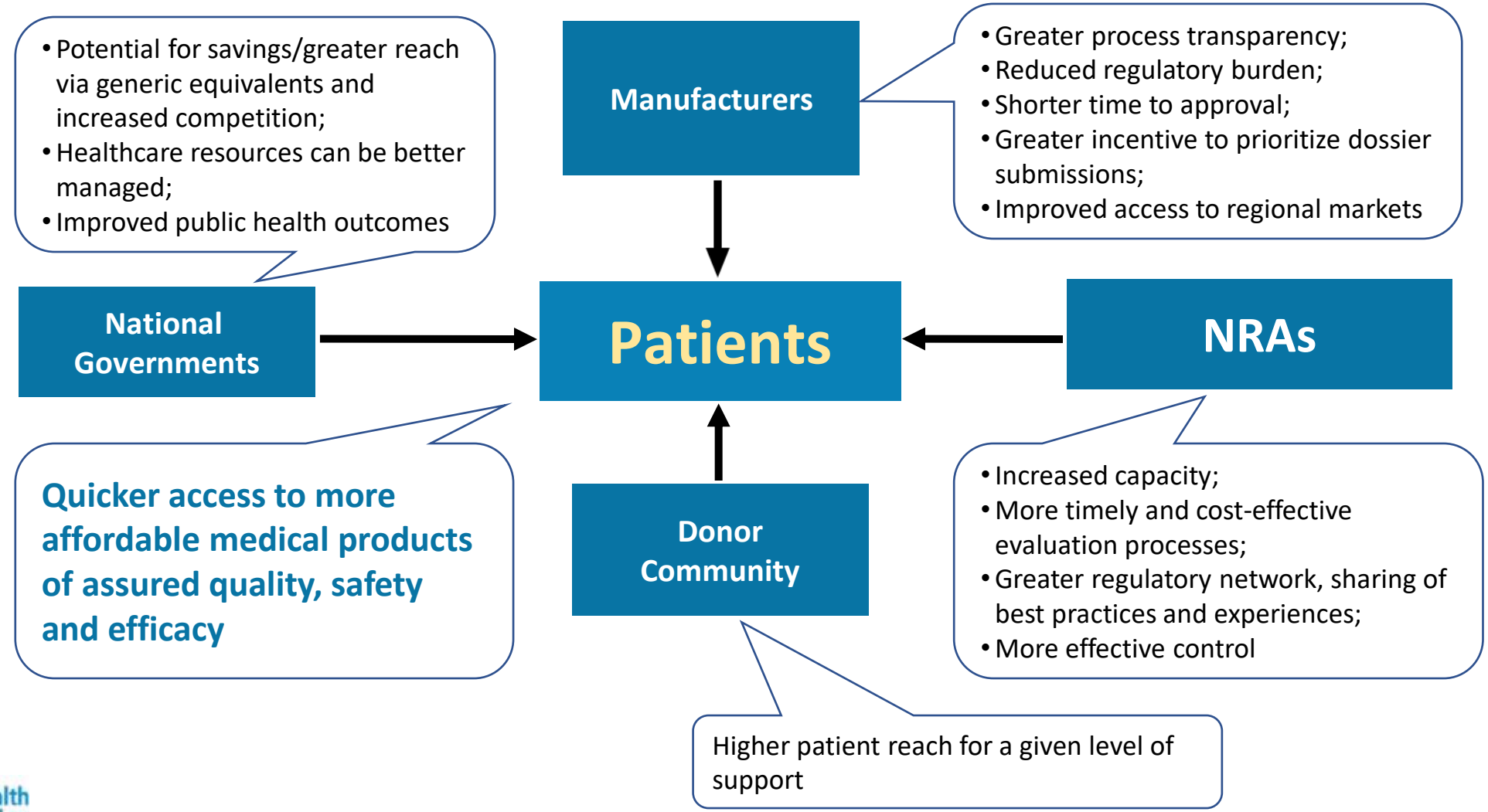
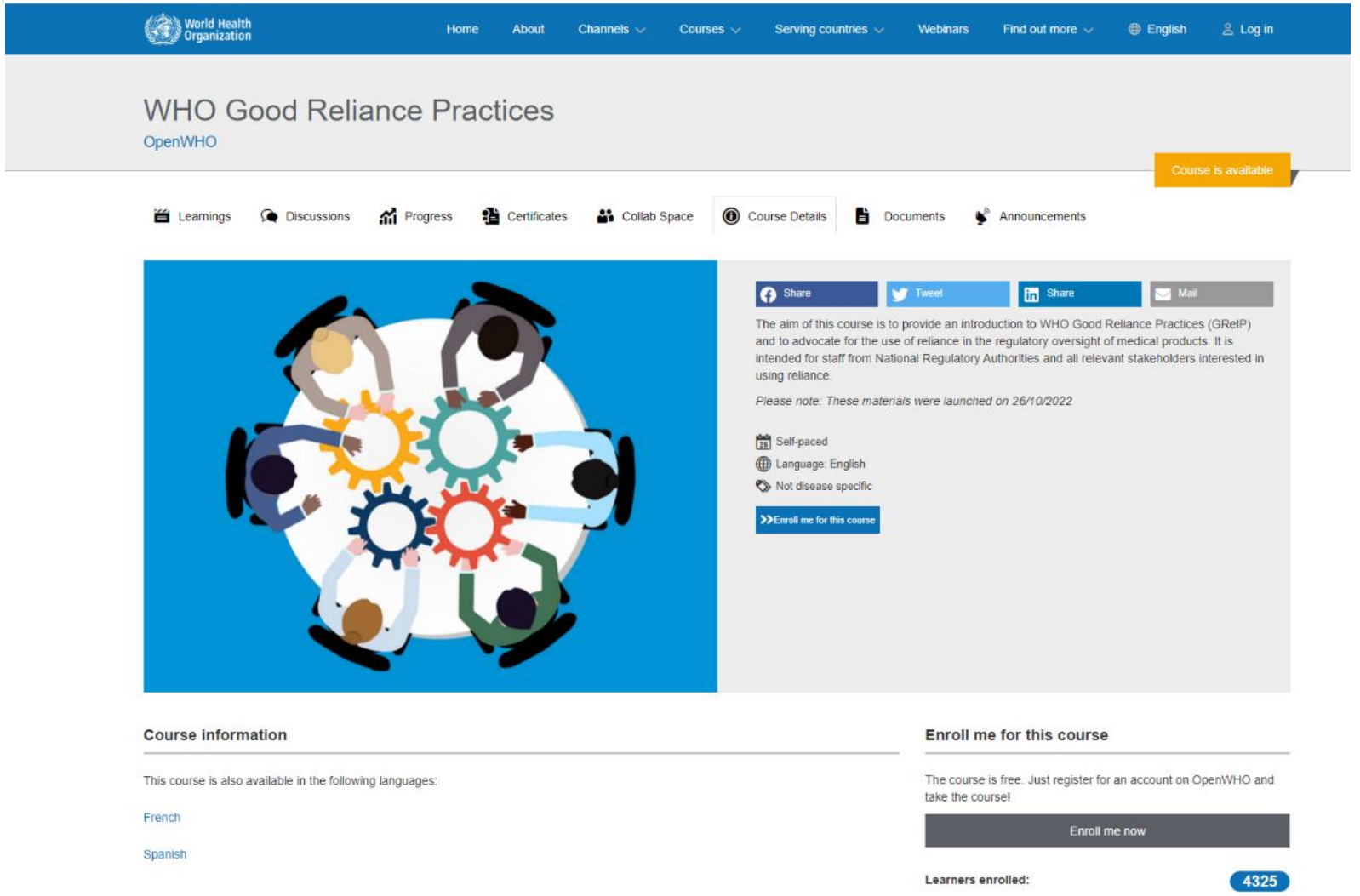
Patient-centric approach is “CENTRAL” in the regulation of medical products based on reliance



WHO Good Reliance Practices



Short eLearning Module of main principles and examples of reliance launched in October 2022 https://openwho.org/courses/good-reliance-practices

Now available in English, Spanish and French languages

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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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