World Health Organization

Collaborative Registration Procedure for WHO PQ-ed medicines and its impact on accelerated registration and timely access to quality-assured medicines in LMICs

Hiiti Sillo

Unit Head, *Regulation and Safety*
Department of Regulation and Prequalification, WHO

FDA - USP/PQM+ Webinar

Access to medical products – global challenge

- Good health is impossible without access to medical products

- Reasons for limited/insufficient access are numerous
  - ✓ insufficient/inadequate regulatory capacity
  - ✓ lack of collaboration and work sharing between countries in regulation of medical products

Addressing regulatory capacity gaps in countries

- 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 56 countries (29%) have regulatory systems at GBT maturity level 3/4
    - See: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**

World Health Organization

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)

How to “transfer/translate” the regulatory information from trusted sources to facilitate in-country approval of medical products?

The Sixty-seventh World Health Assembly Resolution 67.20 recognized that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products

- WHO Prequalification and approval by “SRAs” provide good basis for informed national decision making;
- How do we get the prequalified and “SRA”- approved products to the patients faster, and more efficiently?
- How do we ensure continued supply of quality-assured products post-registration?

World Health Organization

CRP is a good example of reliance in facilitating in-country regulatory approval of medical products

- WHO Prequalification and approval by “SRAs” provide a good basis for informed national decision making

  - ✓ Accelerating access by patients faster, and more efficiently
  - ✓ Ensuring continued supply of quality-assured products post-registration

- As of August 2022, significant increase of countries implementing CRP
  - ✓ 57 in PQ CRP medicines and vaccines
  - ✓ 45 in SRA CRP medicines and vaccines
  - ✓ 22 in PQ CRP IVDs

Regulatory information and knowledge could be transferred through facilitated pathways

WHO PQ collaborative registration procedure

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

"SRA" collaborative registration procedure

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

Regional regulatory harmonization initiatives and networks

African Medicines Regulatory Harmonization Initiative (AMRH)

ASEAN SIAHR Project

World Health Organization

Facilitated Registration Pathways – key principles

- Voluntary;
- Product and registration dossier in countries are “the same” as **prequalified by WHO or approved by “SRAs”;**
- Shared confidential information to support NRA decision making in **exchange for accelerated registration process;**
- “Harmonized product status” is monitored and maintained.

Win-win outcomes for all concerned stakeholders - patients in the focus

NRAs

- Having data well organized in line with PQ requirements;
- Availability of unredacted WHO assessment, inspection and performance evaluation outcomes to support national decisions and save internal capacities;
- Having assurance about registration of “the same” product as is prequalified;

WHO

- Prequalified products are faster available to patients;
- Feed-back on WHO prequalification outcomes;

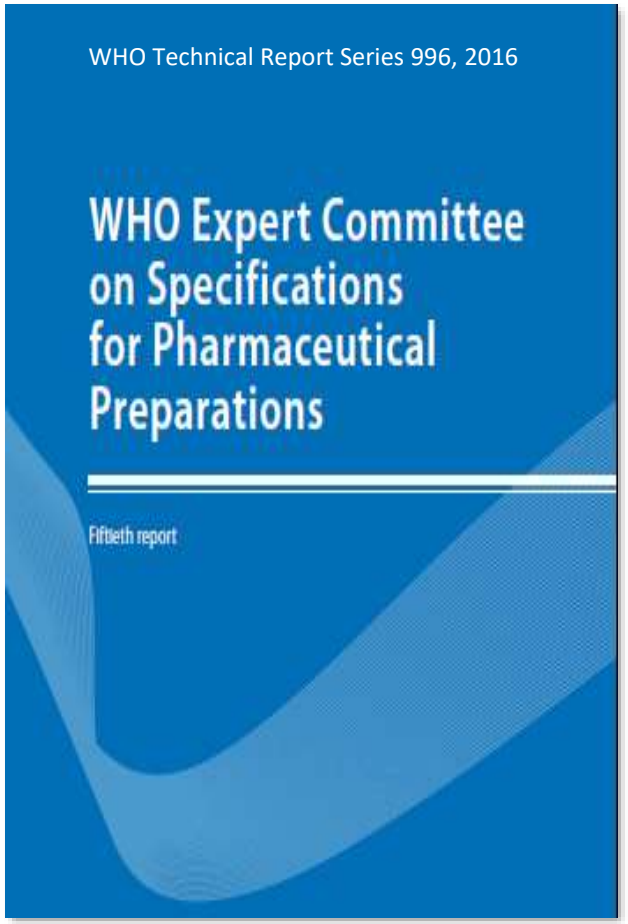
Manufacturers

- Harmonized data for PQ and national registration;
- Facilitated interaction with NRAs in assessment, inspections, performance evaluations;
- Accelerated and more predictable registration;
- Easier post-registration maintenance;

Procurers

- Time, assurance, availability.

Applicable guidelines for CRP



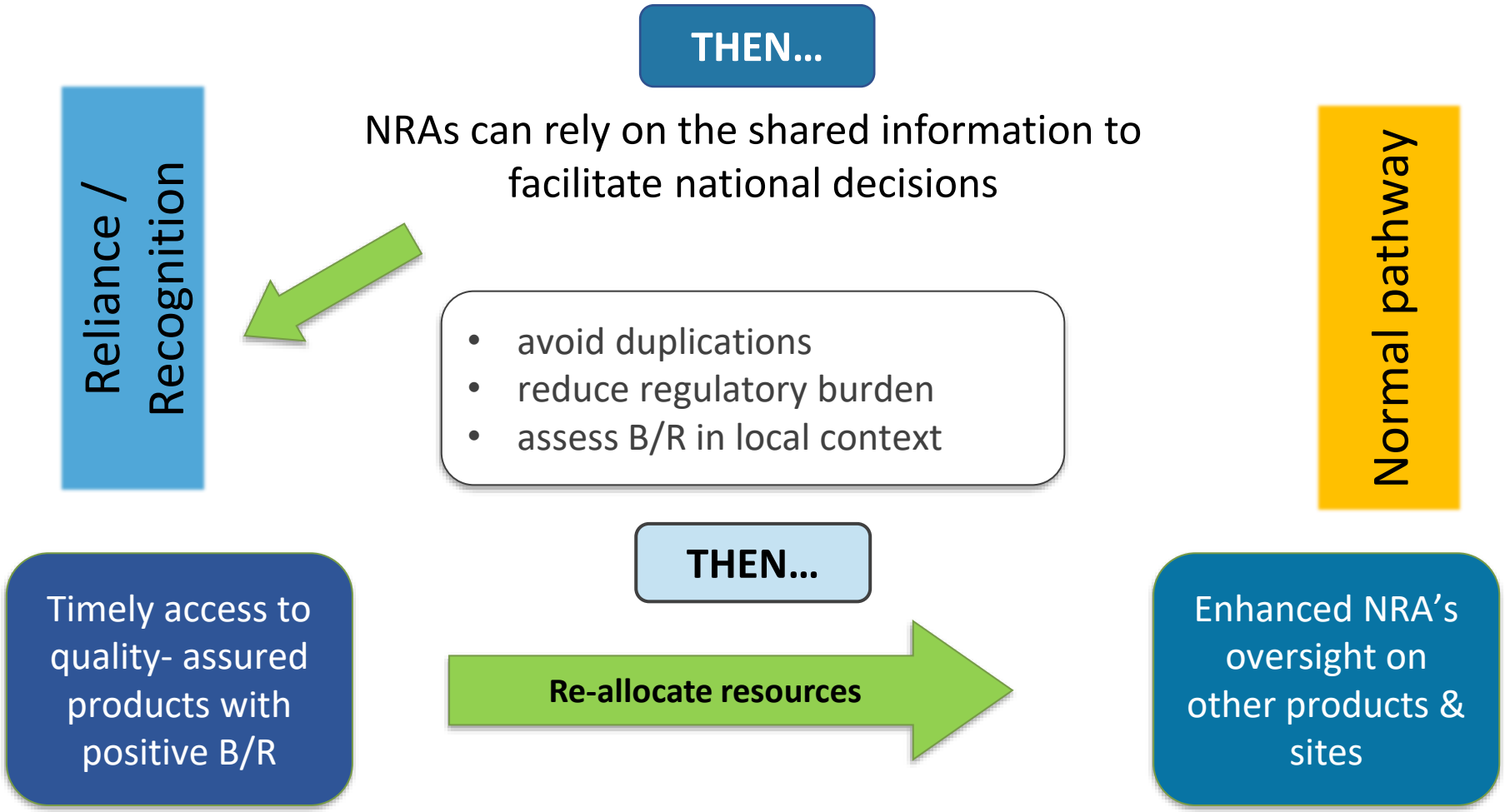
http://apps.who.int/iris/bitstream/handle/10665/255338/9789241209960-eng.pdf?sequence=1

Annex 8

Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines

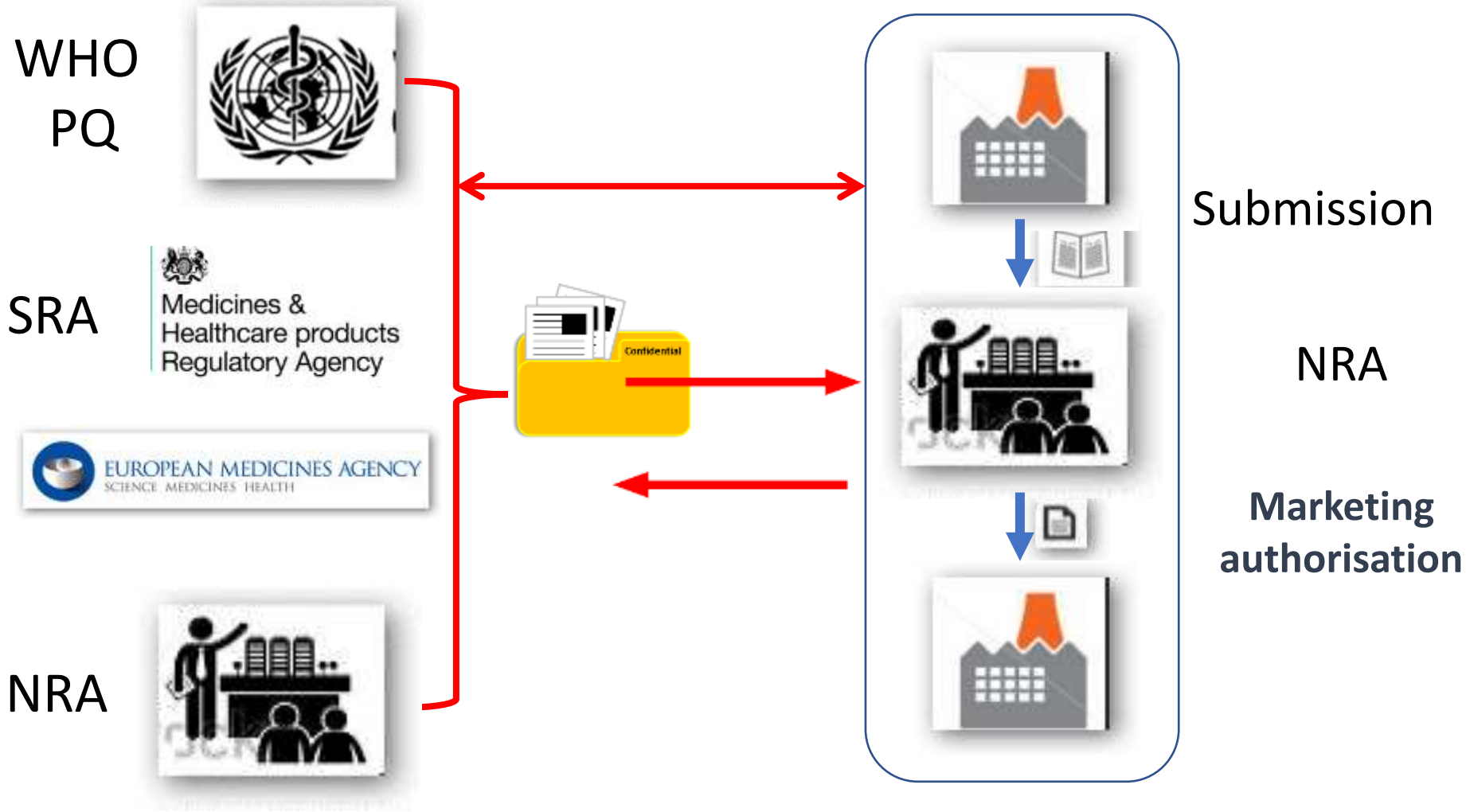
World Health Organization

If we share information (assessments, inspections, testing) for WHO PQ-ed or “SRA”-approved products



World Health Organization

How does the collaborative procedures work?



World Health Organization

PQ CRP: 56 Participating NRAs, plus 1 Regional Economic Community

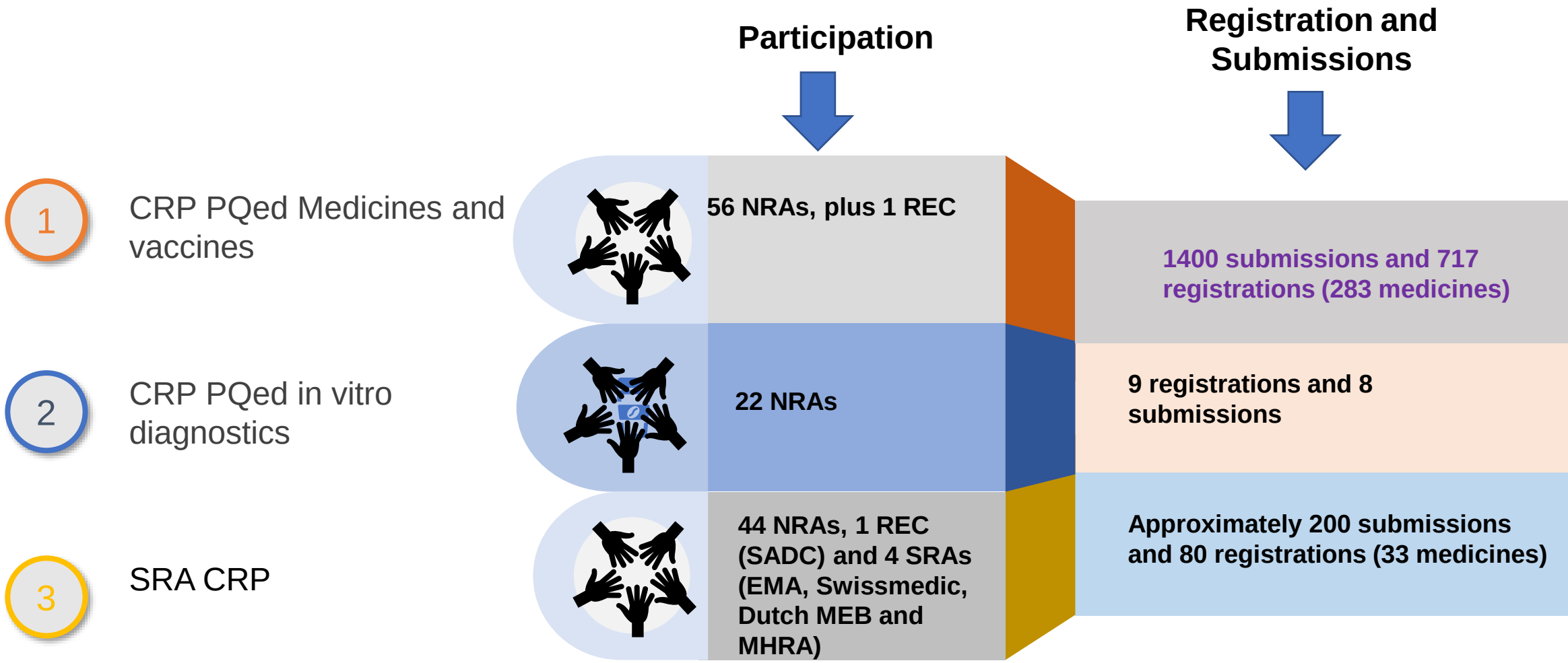
As of August 2022

Angola
Armenia
Azerbaijan
Bangladesh
Belarus
Botswana
Burkina Faso
Bhutan
Burundi
Cameroon
Cape Verde
***Caribbean Community (CARICOM)**
Comoros
Cote d'Ivoire
Dem. Rep. Congo
Eritrea
Ethiopia
Gabon
Georgia
Ghana
Kazakhstan
Kenya
Kyrgyzstan
Lao PDR
Madagascar
Malaysia
Maldives
Malawi
Mali
Mauritania
Moldova
Mozambique
Namibia
Nepal
Nigeria
Pakistan
Philippines
Republic of Congo
Rwanda
Sao Tome and Principe
Senegal
Sierra Leone
South Africa
Sri Lanka
Sudan
Tanzania
Thailand
The Gambia
Timor-Leste
Togo
Uganda
Ukraine
Uzbekistan
Yemen
Zambia
Zanzibar
Zimbabwe

* CARICOM
Member States: Antigua and Barbuda, Bahamas, Belize, Dominica, Grenada, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St Vincent and the Grenadines, Suriname and Trinidad and Tobago
Associate Member States: Anguilla, Bermuda, British Virgin Islands, Cayman Islands and Turks and Caicos Islands

World Health Organization

CRP in facilitating in-country regulatory approval of medical products

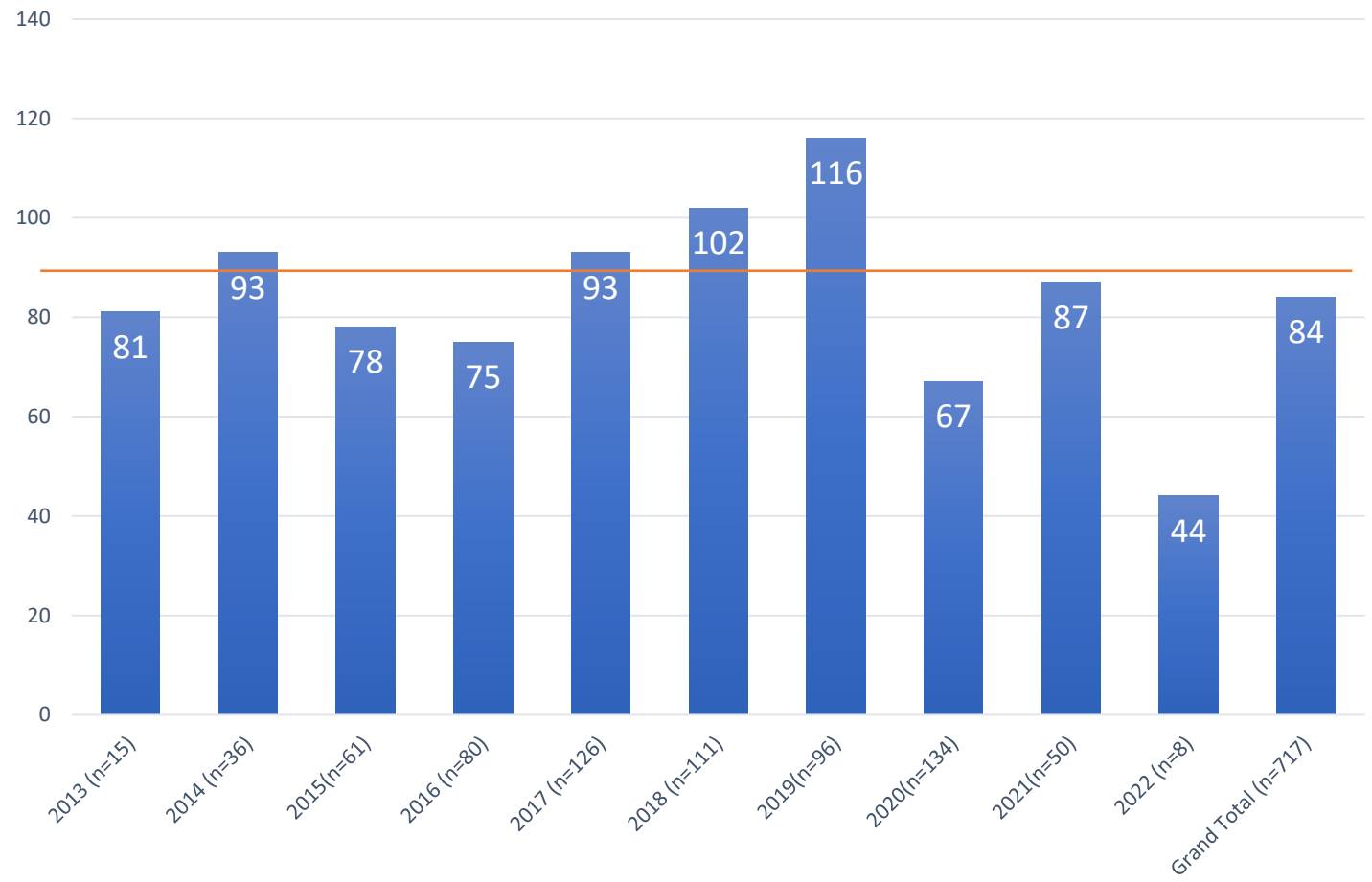


Collaborative Registration Procedure: 52 Participating NRAs, plus 1 Regional Economic Community in 4 continents

Total registrations: 717
As of August 2022

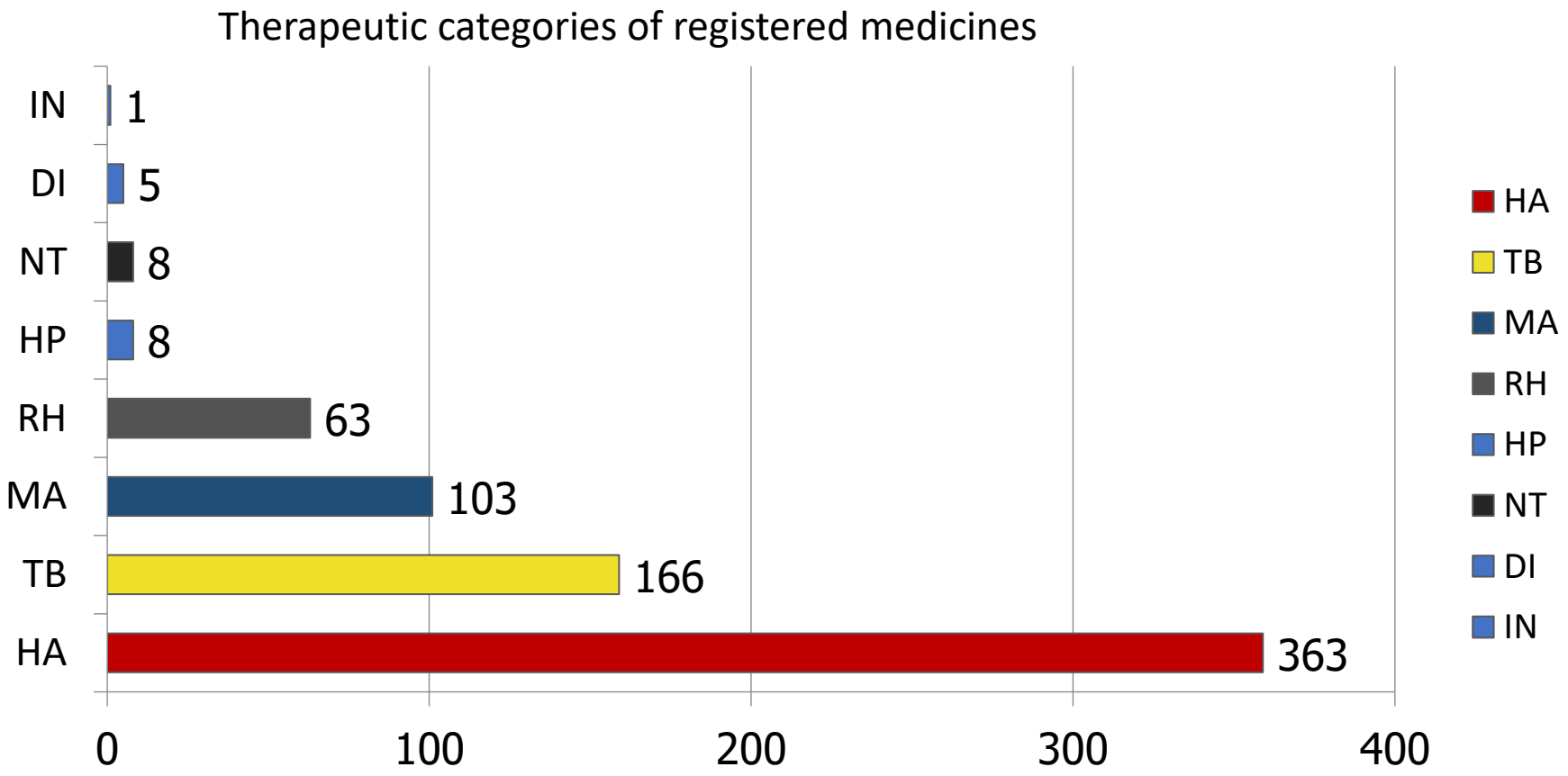
90 days TARGET

*Including regulatory time and applicant time



World Health Organization

PQ CRP: Registrations by therapeutic categories



World Health Organization

Total registrations: 717
(As of August 2022)

Concluding remarks

- Access to medical products is a never-ending challenge and shared responsibility among governments, NRAs, SRAs and industry
- Not a single regulator anymore can fulfil all regulatory work alone and independently
- The future of medical products regulation is on convergence, harmonization, collaboration and networking based on **reliance and trust**
- CRP has proved to be one of the solid examples of enhancing access

World Health Organization

Thank you for your attention

Hiiti Sillo
Unit Head
Regulation and Safety, WHO
Email: silloh@who.int