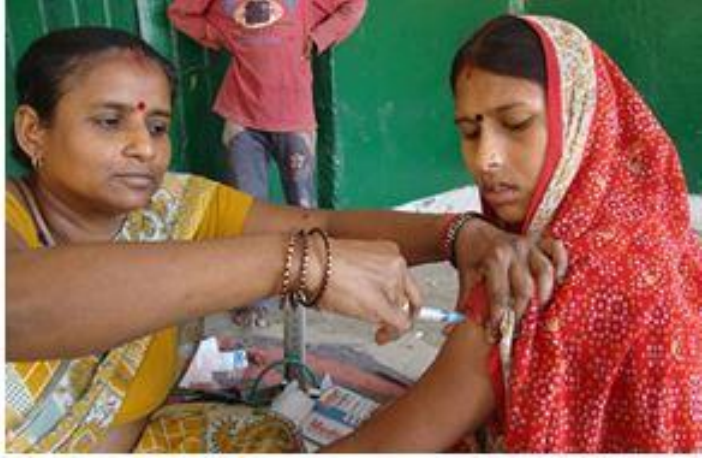
World Health Organization



Collaborative Registration Procedure for Advancing Vaccines' Registration in Emerging Countries

19th Annual General Meeting
DCVMN

31 October 2018
Kunming, China

Emer Cooke
Director
Regulation of Medicines and other Health Technologies

Key Themes of WHO’s 13th General Programme of Work 2019-2023

Mission

Promote Health - Keep the World Safe - Serve the Vulnerable

Strategic Priorities

Health Coverage: 1 billion more people with health coverage
Health Emergencies: 1 billion more people made safer
Health Priorities: 1 billion lives improved

NEW Cluster

Access to Medicines, Vaccines and Pharmaceuticals (MVP)
Dr. Mariângela SIMÃO, Assistant Director General

at EB 2019

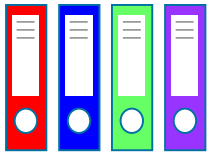
Roadmap on **access** to medicines and vaccines
http://www.who.int/medicines/access_use/road-map-medicines-vaccines/en/

WHO Regulatory Activities: Focus on **Access** and Outcomes

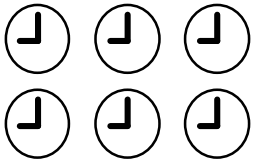
Ensuring normative and technical excellence drives impact at country level

World Health Organization

Technologies, Standards and Norms	Regulatory Systems Strengthening	Prequalification Programme	Safety & Vigilance
• Set global norms and standards (written & physical) and nomenclatures • Increase common understanding on regulatory requirements by authority and manufacturer • Standardize approach used by quality control labs	• Set effective and efficient regulatory systems in LMICs through collaborative & harmonized approaches with reliance principles • Increase confidence in medical products produced in LMICs	• Assure safety, quality, efficacy & appropriateness of medical products used in LMICs: vaccines, medical devices, cold chain equipment, vector control products & in vitro diagnostics • Increase competition to shape the market	• Increase knowledge of real life adverse events and coordinate actions taken against adverse events • Mitigate risks and protect against substandard / falsified products • Contain antimicrobial resistance



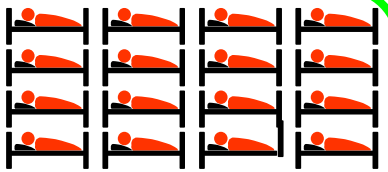
Decreased regulatory burden



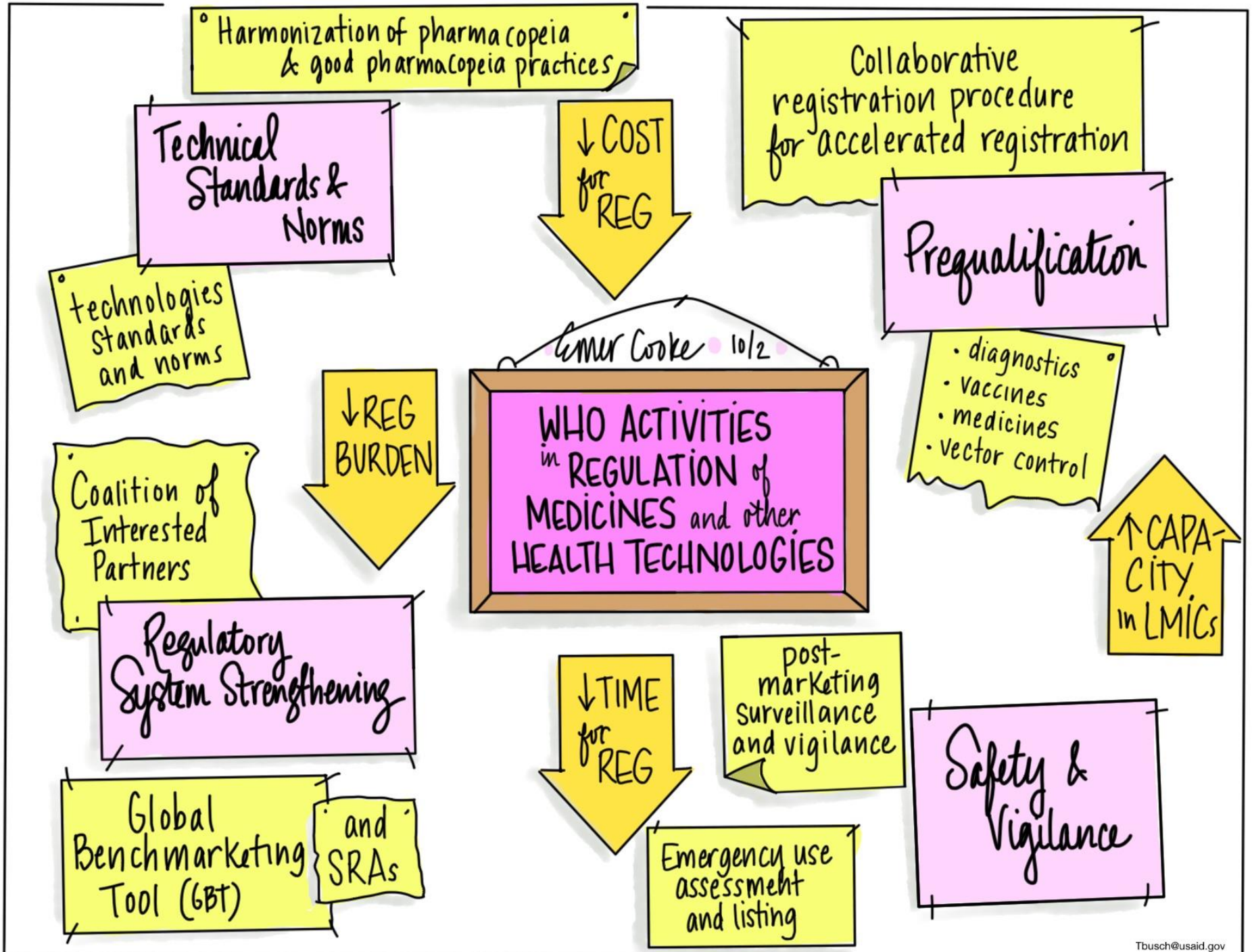
Reduced time for regulation

Increased regulatory capacity in LMIC

Decreased cost of regulation



Reduced mortality and morbidity



Tbusch@usaid.gov

From Prequalification to **Access**:

How do we get quality vaccines to every child, man and woman faster and more efficiently?

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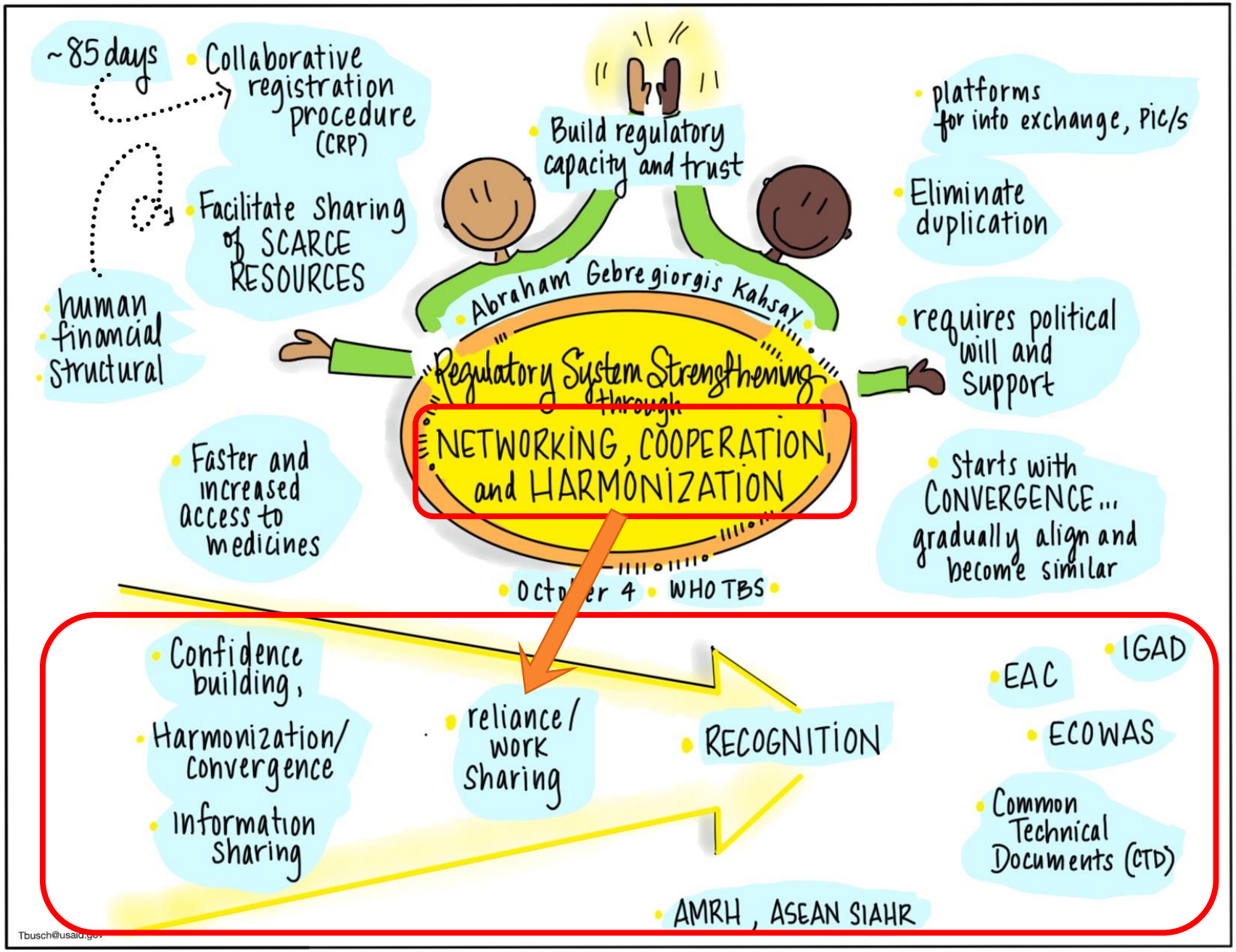
Collaboration, Reliance, Harmonization, Information Sharing



Tbusch@usaid.gov

Accelerated registration through Collaborative Registration Procedures (CRP)

World Health Organization

Objectives:

- to facilitate the assessment and accelerate national registration of Prequalified products
- to accelerate registration of health products that have already received approval from a “stringent regulatory authority”

Principles:

- ✓ Voluntary
- ✓ Sovereignty
- ✓ Identicality
- ✓ Co-operation
- ✓ Reliance
- ✓ Monitoring and maintenance

Sovereignty: Participating NRAs agree to respect principles, but national requirements still apply, decision remains national decision

Reliance: WHO PQT share the assessment reports, inspection reports and laboratory results with participating NRAs

CRP Participating NRAs

World Health Organization

As at 30 June 2018

Armenia
Botswana
Burkina Faso
Burundi
Cameroon
*Caribbean Community (CARICOM)
Cote d'Ivoire
Dem. Rep. Congo
Eritrea
Ethiopia
Georgia
Ghana
Kenya
Kyrgyzstan
Lao PDR
Madagascar
Malawi
Mali
Mozambique
Namibia
Nigeria
Pakistan
Philippines
Senegal
Sierra Leone
South Africa
Sri Lanka
Tanzania
Thailand
Uganda
Ukraine
Zambia
Zanzibar
Zimbabwe

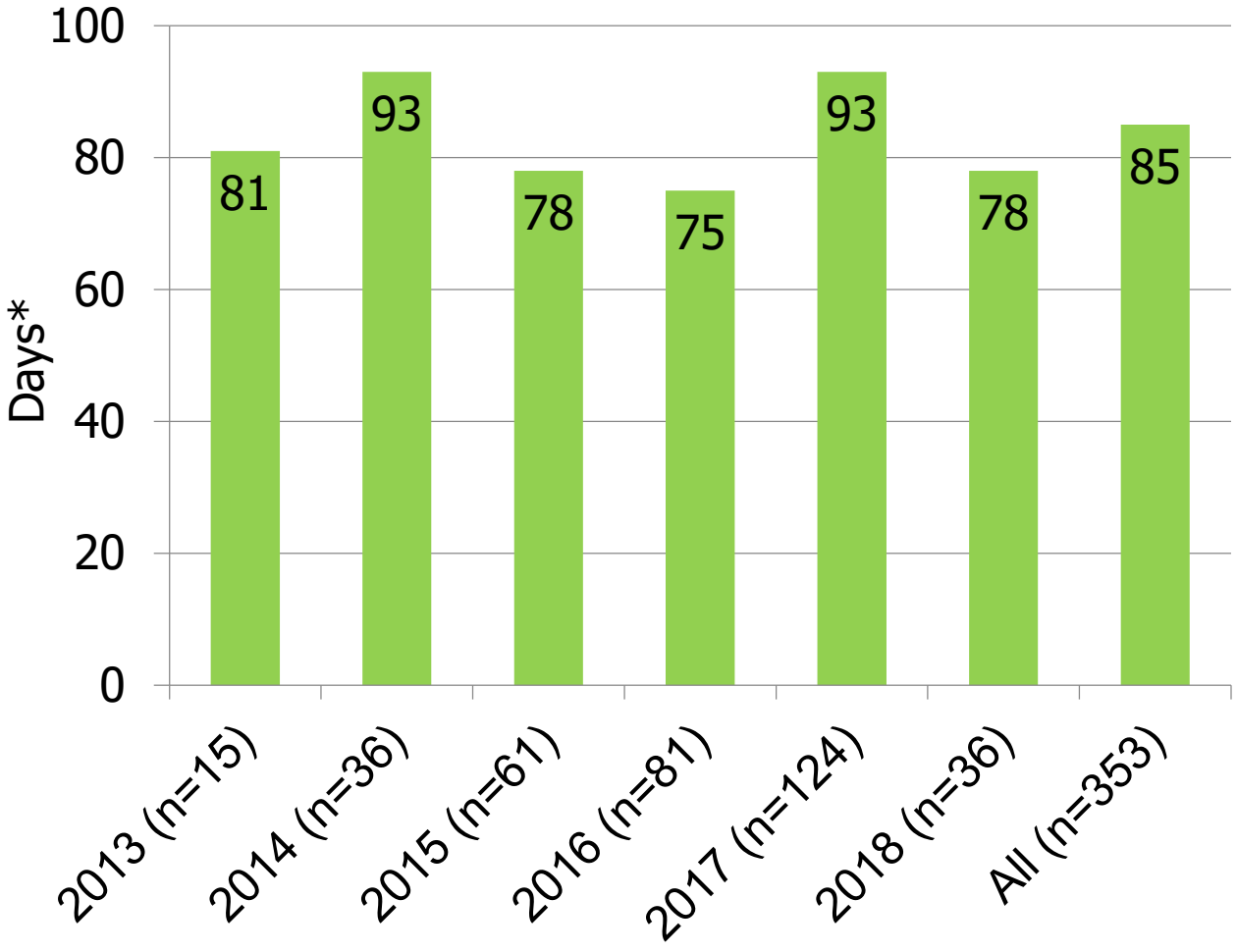
* CARICOM

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

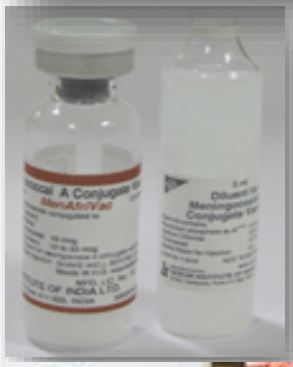
CRP: Median time to registration
(> 350 registrations for PQ Medicines)

*Including regulatory time and applicant time



But what about access to vaccines?
some examples of collaboration

World Health Organization



MenAfriVac (2010) - How it worked:

- Regulatory support from Health Canada (HC) and Indian DCGI
- Fast track, expedited procedure, prequalification approach, using HC/DGCI assessment (PQed in 5 months)
- Workshop in AFRO for sharing of reports that were the basis for PQ

Benefits:

- Assessment resources saved and targeted to other activities, for example, strengthening post-marketing surveillance

Successful registration of MenAfriVac in 26 countries of the meningitis belt (2011)

Facilitating access to vaccines in Public Health Emergency (PHEIC or graded emergency)

World Health Organization

Polio end-game strategy

SAGE (2012) recommendation to withdraw type 2 component of OPV in all countries, facilitated by the introduction of at least one dose of IPV	Mapping regulatory status in all countries: 1) Already licensed 2) Accept PQed vaccine (waive) 3) Facilitated registration	Facilitated registration: "Joint review" 1) Standard: EMRO (8 countries) 2) PQ approach: AFRO (19 countries) SEARO (3 countries)

Facilitated registration of two vaccines, IPV and bOPV, in all countries

Experiences of CRP for Vaccines 2016/7:
Ukraine, Zimbabwe, DRC, Ethiopia

World Health Organization

 Ukraine	2016 6 vaccines applied	5 registered in < 12 months
 Zimbabwe	2017 1 vaccine BCG (India)	Registration still pending
 DRC	2017 1 vaccine DTwP-HepB-Hib (Korea)	Registration still pending
 Ethiopia	2017 1 Vaccine DTwP-HepB-Hib (Korea)	Registered About 6 months

Experiences of CRP for Vaccines:
2017: workshop in Accra on oral cholera vaccine

- CRP workshop on registration of PQed oral cholera vaccine manufactured in Korea
- Participating NRAs:
  Ghana, Nigeria, Tanzania, Uganda and representatives from CARICOM
- Oral Cholera vaccine registered in:

Nigeria in June 2018 - < 3 months

CARICOM* in April 2018 - < 5 months

* 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

Experiences of CRP for Vaccines: 2018

 Thailand	2018 4 Pqed vaccines successfully registered	Reduced registration times by more than 6 months, "excellent reports"
 Ukraine	2018 Tetanus (Indonesia)	Documentation ready to be shared
 Belarus	2018 DTwP-HepB-Hib (Korea)	Documentation ready to be shared

Other "mature" authorities requesting reports, particularly for emergency products

Work on Ebola vaccine ongoing with AVAREF members

Optimizing CRP for vaccines (1)

- Mapping of current regulatory pathways in countries critical to ensure efficient use of resources
  - Countries accepting PQed vaccines supplied through UN
  - Countries ready to accept CRP
  - CRP Agreements extended to vaccines if necessary and focal points designated

- Identification of possible constraints for implementation of the procedure in countries.

  Need for local agent in countries?

  understanding of inspection and testing requirements,

  interest from manufacturers to submit an application?

Optimizing CRP for vaccines (2)

World Health Organization

Focussing resources

- Need to define priority vaccines and countries: for example,
  - priority vaccines representing major public health benefits or vaccines to contain an outbreak or vaccines under shortages
  - countries with long timelines, specific national requirements
- PQ to improve preparedness for sharing reports
- Joint review option may also facilitate registration (not CRP)

But

- Dossiers need to be first submitted in countries
  - Interest from countries that will benefit from the review - future “champions”
  - Adjustments may be needed depending on knowledge base of countries

Key Messages

- Strong and efficient Regulatory systems use concepts such as reliance, work-sharing and international collaboration
- Rich portfolio of concepts, tools, networks and enablers now exist – e.g.
  - Good Regulatory Practices
  - Collaborative Registration Procedures
  - Joint reviews, Regional networks…
- More work needed to translate into practical realities for vaccines
- "Political will" and understanding as well as "regulatory will" are crucial
  - the power of the patient and stakeholder voice
  - the role of regulatory champions
- Opportunities to streamline in other areas, e.g., post approval changes/variations and inspections

World Health Organization

A world where every child, man and woman has **access** to the quality essential medicines, vaccines and other health products they need to lead a healthy and productive life.

CRP is a key enabler

谢谢

thank you for your attention

Emer Cooke
Director, Regulation of Medicines and other Health Technologies