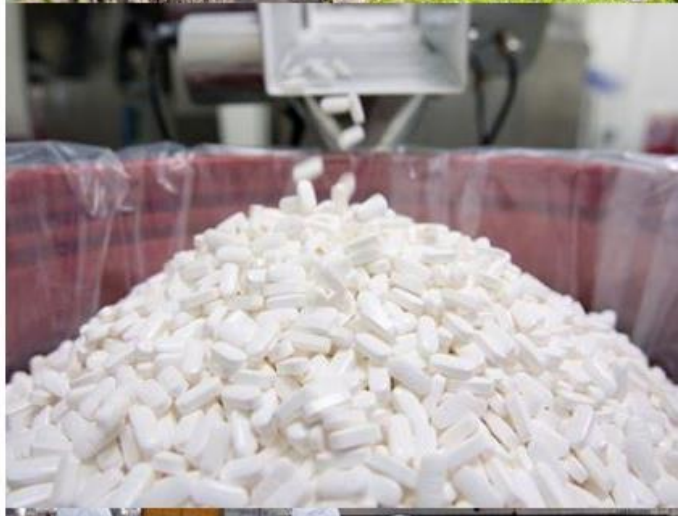
World Health Organization

Improving Access to Medical Products through Strengthening Regulatory Systems

IX PANDRH Conference

24 October 2018
San Salvador, El Salvador

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

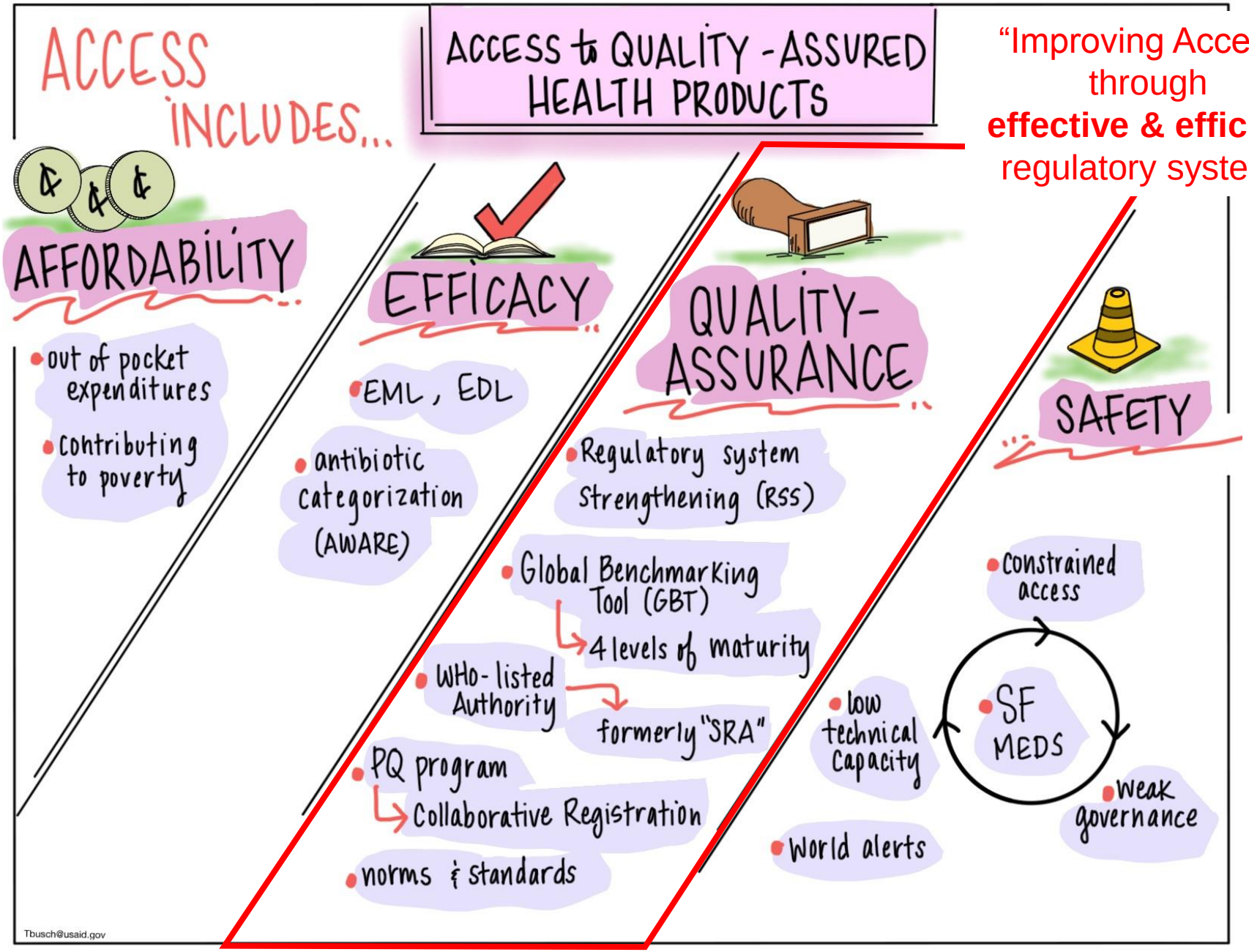
Strategic Priorities

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

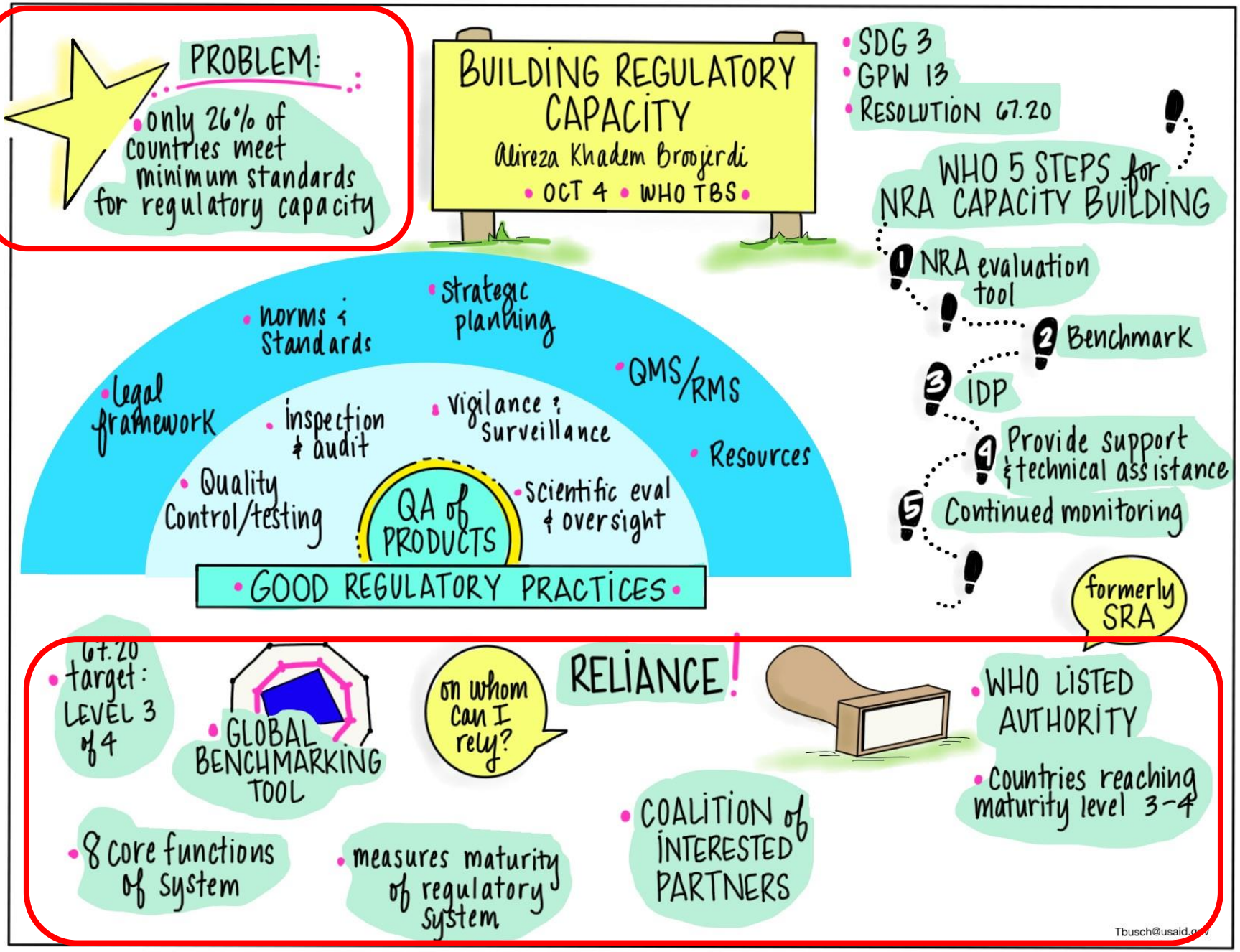
NEW Cluster — Access to Medicines, Vaccines and Pharmaceuticals (MVP)
Dr. Mariângela SIMÃO, Assistant Director General

at EB 2019 — Roadmap on access to medicines- to be presented
http://www.who.int/medicines/access_use/road-map-medicines-vaccines/en/

FOCUSING ON UHC – How do we improve Access?



WHO Regulatory Systems Strengthening and Capacity Building



Moving Towards WHO-Listed Authority (WLA)

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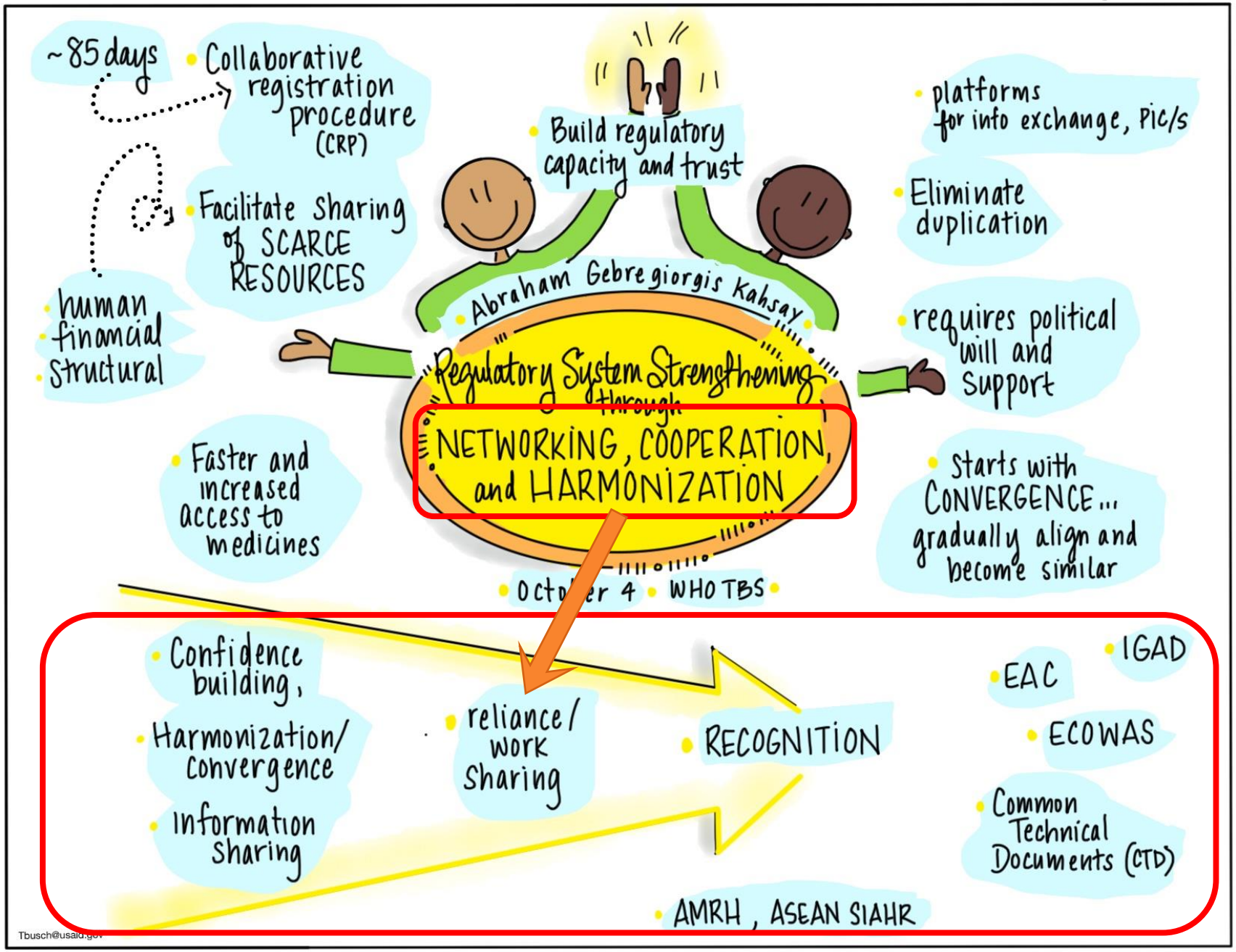
'Stringent Regulatory Authority' (SRA):

- originally based on ICH membership
- developed to promote reliance and guide procurement decisions
- widely used and recognized

Growing recognition that change was needed:

- Term SRA be replaced by ***WHO-Listed Authority (WLA)***
- Currently identified "SRAs" to be regarded as WLAs
- Additional NRAs to be designated based on WHO Global Benchmarking Tool (GBT) plus completion of confidence-building process
- Procedure for listing to be developed through a broader consultation process
- Targeting early 2019 for adoption, together with an introduction of WHO GBT (version VI)
- Voluntary process – undertaken at request of country with the understanding that outcome (but not details) to be made public

Collaboration, Reliance, Harmonization, Information Sharing



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How do we get the needed quality products to these patients faster, and more efficiently?

Accelerated registration through Collaborative Registration Procedure (CRP)

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

CRP Participating NRAs – PQ medicines

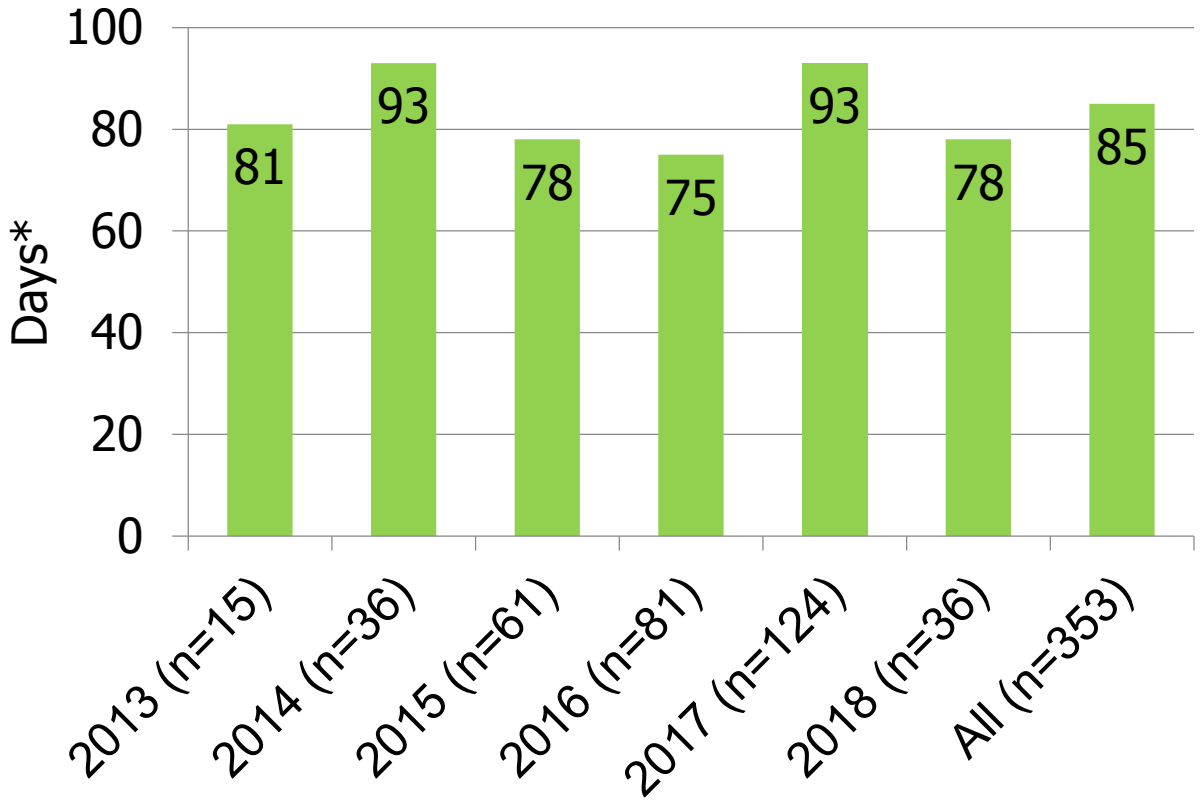
As at 30 June 2018

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

*Including regulatory time and applicant time



Without CRP:

Approximately 5 years to get global approval in 100+ countries for a single variation for a vaccine with 75+ repetitive reviews & questions

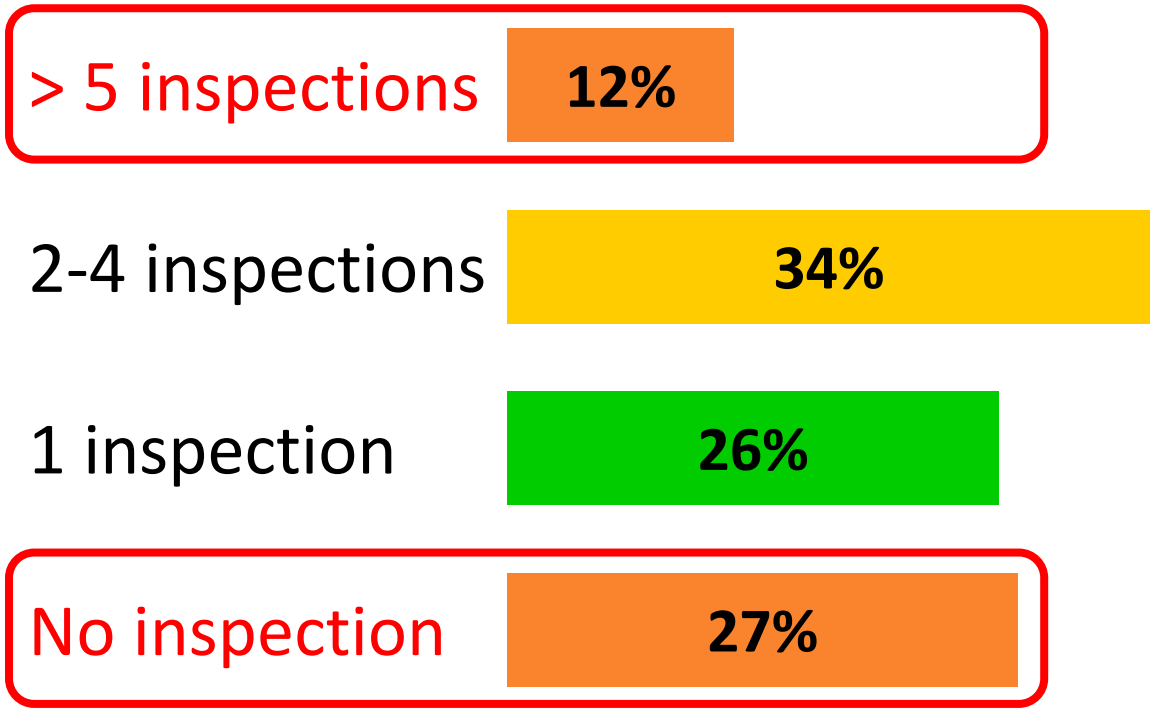
Source: Paul Dearden, Head, International, Regulatory Policy and Intelligence, AbbVie, UK. CIRS Workshop, Pretoria, South Africa.

GMP Inspection Workload

Manufacturing sites

Pre-ICDRA Workshop 4

Impact of work sharing and utilization of risk-based inspections on access to medicines



Industry and NRA's agree:

- Confirming compliances without undertaking an on-site inspection avoids duplication of work, reduces regulatory burden and allows more efficient use of inspection resources
- Informed decision on compliances can be made based on the work of another NRA

Source: Dr.-Ing. Stephan Rönninger, Amgen Europe GmbH on behalf of EFPIA, , 18th Pre-ICDRA Conference, Dublin Ireland

Changing the Paradigm - 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
  - Good Regulatory Practices
  - Collaborative Registration Procedures
  - Medical Device Single Audit Program (MDSAP)
- More work needed to translate into practical realities – key role of PANDRH
- Also opportunities to streamline in other areas e.g. post approval changes/variations
- Collaboration not Competition – the new reality to enable patient access

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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.

muchas gracias

thank you for your attention

Emer Cooke
Director, Regulation of Medicines and other Health Technologies