Initiatives and Progress Towards Harmonization

World Health Organization

Initiatives and Progress Towards Harmonization

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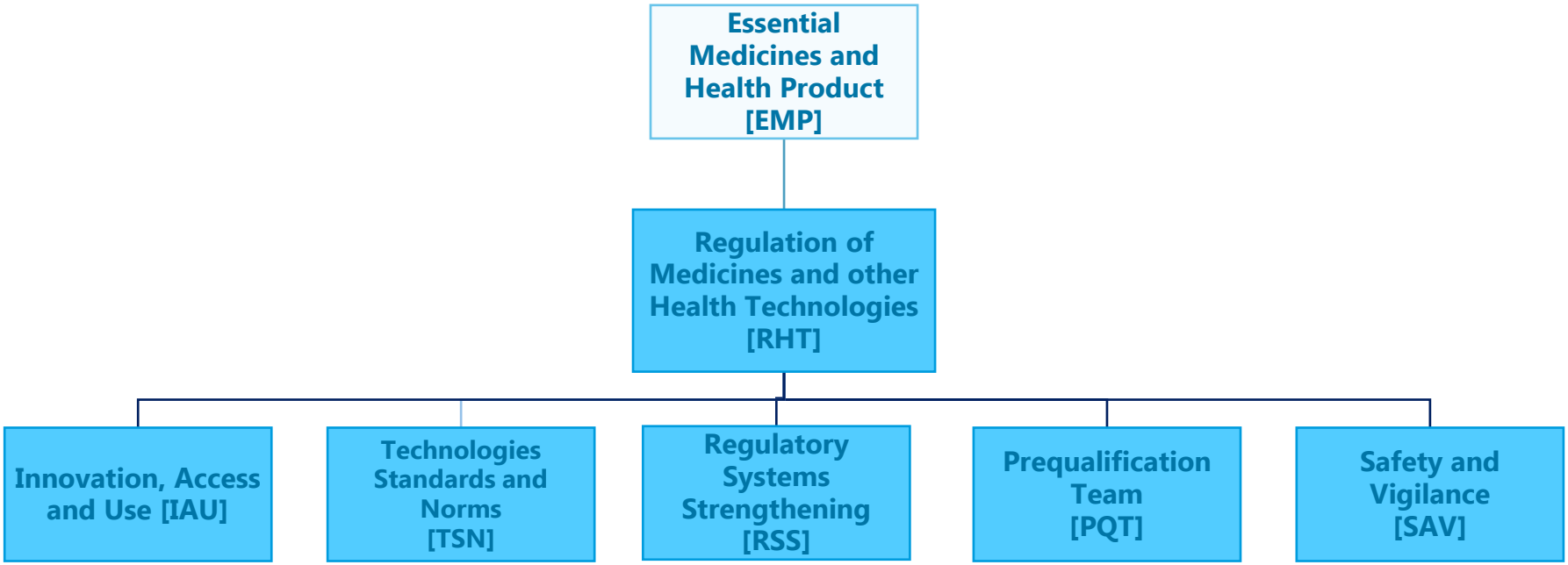
Who are we?


Essential Medicines and Health Product [EMP]
Regulation of Medicines and other Health Technologies [RHT]
Innovation, Access and Use [IAU]
Technologies Standards and Norms [TSN]
Regulatory Systems Strengthening [RSS]
Prequalification Team [PQT]
Safety and Vigilance [SAV]

What is the goal?

For manufacturers

A common regulatory dossier for manufacturers?

- At submission: common standards
- Over time: common standards and common procedures

For agencies

Quality products, supported by quality dossiers

Faster assessments

For WHO

Increased reliance among regulators, avoiding duplication of effort

Harmonisation of standards

World Health Organization

WHO Activities

- ICH
- IGDRP-IPRF
- WHO Expert committees
- Regulatory strengthening activities

Observations

- Different bioequivalence and biowaiver requirements
- Different acceptable reference products in different countries.

Reliance among Regulators

Reliance among Regulators

Information sharing and reliance

Reliance verses recognition within WHO-RHT

Recognition

The PQT - SRA procedure

Listing of PEPFAR, EU Art 58 products

Use of EDQM CEP to support Drug Product applications.

EU oversight of manufacturing sites

Reliance

Use of other regulators assessment reports to conduct abridged assessments

Use of other regulators GMP Inspection reports to undertaken Desk reviews to establish compliance

WHO PQT Collaborative Registration procedure

WHO SRA Collaborative procedure pilot

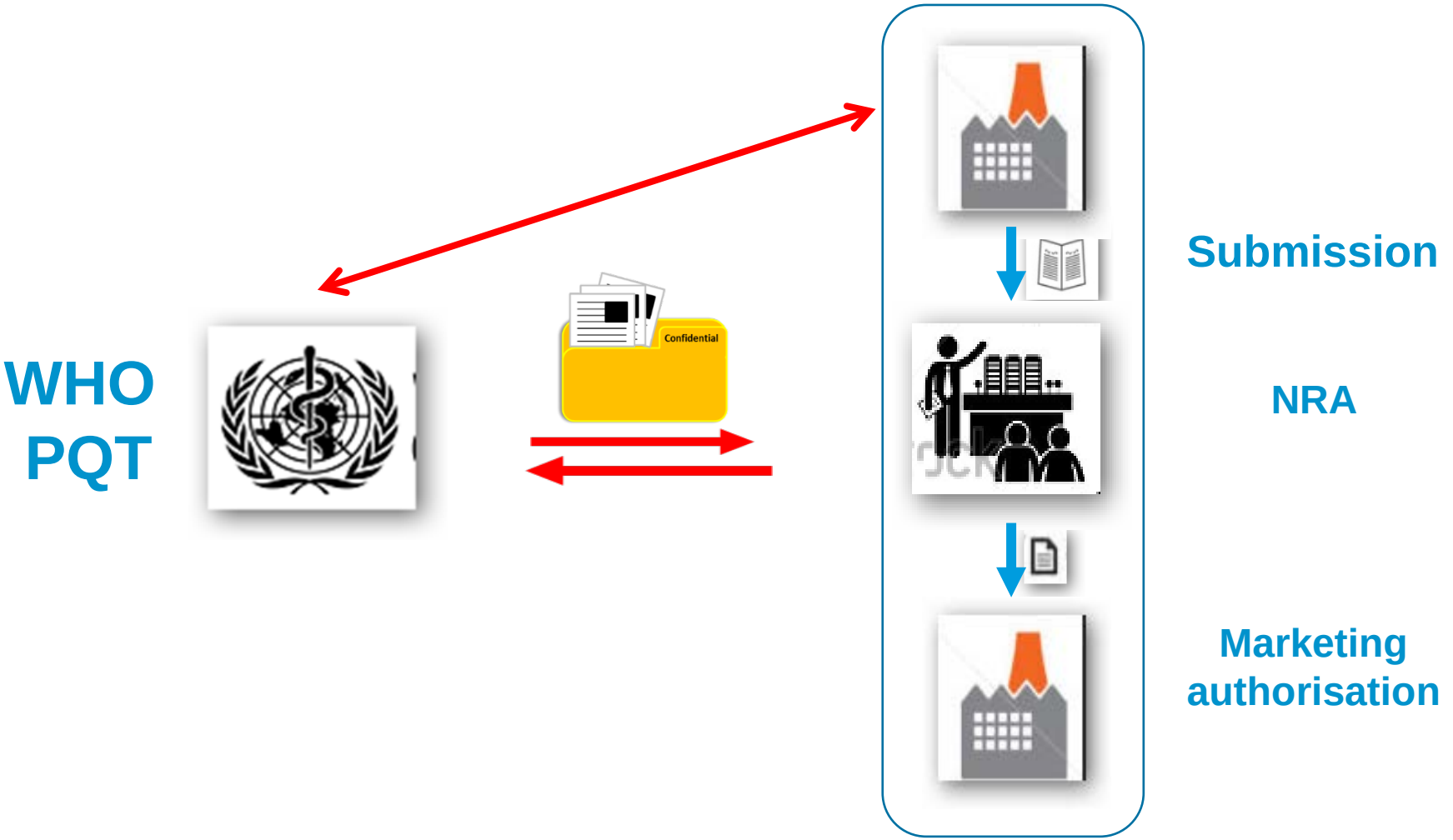
WHO PQ Collaborative Registration Procedure

WHO CRP

- It is for manufacturers of Prequalified Drug Products, to accelerate registration in-country
- It is voluntary
- Shared confidential information to support NRA decision making in exchange for accelerated registration process
- NRA decision within 90 days (Y/N)
- Product and registration dossier in countries are 'the same' as prequalified by WHO.
- 'Harmonized product status' is monitored and maintained

WHO PQ Collaborative Registration Procedure

World Health Organization



WHO PQ Collaborative Registration Procedure

Participating NRAs

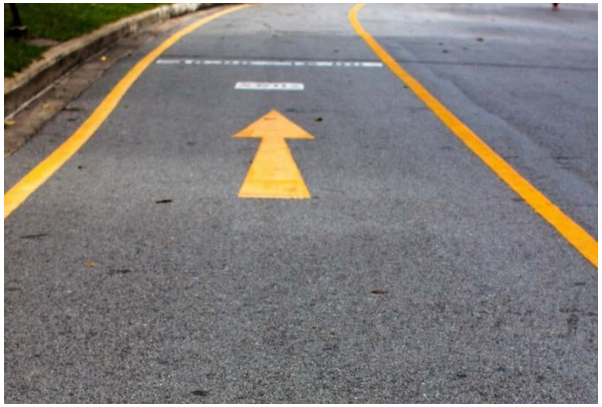
Armenia
Botswana
Burkina Faso
Burundi
Cameroon
*Caribbean Community (CARICOM)
Cote d'Ivoire
Dem. Rep. Congo
Eritrea
Ethiopia
Georgia
Ghana
Kenya
Kyrgyzstan
Lao PDR
Madagascar
Malawi
Mali
Mozambique
Namibia
Nigeria
Philippines
Senegal
Sierra Leone
South Africa
Tanzania
Uganda
Ukraine
Zambia
Zanzibar
Zimbabwe

As at 12 May 2017

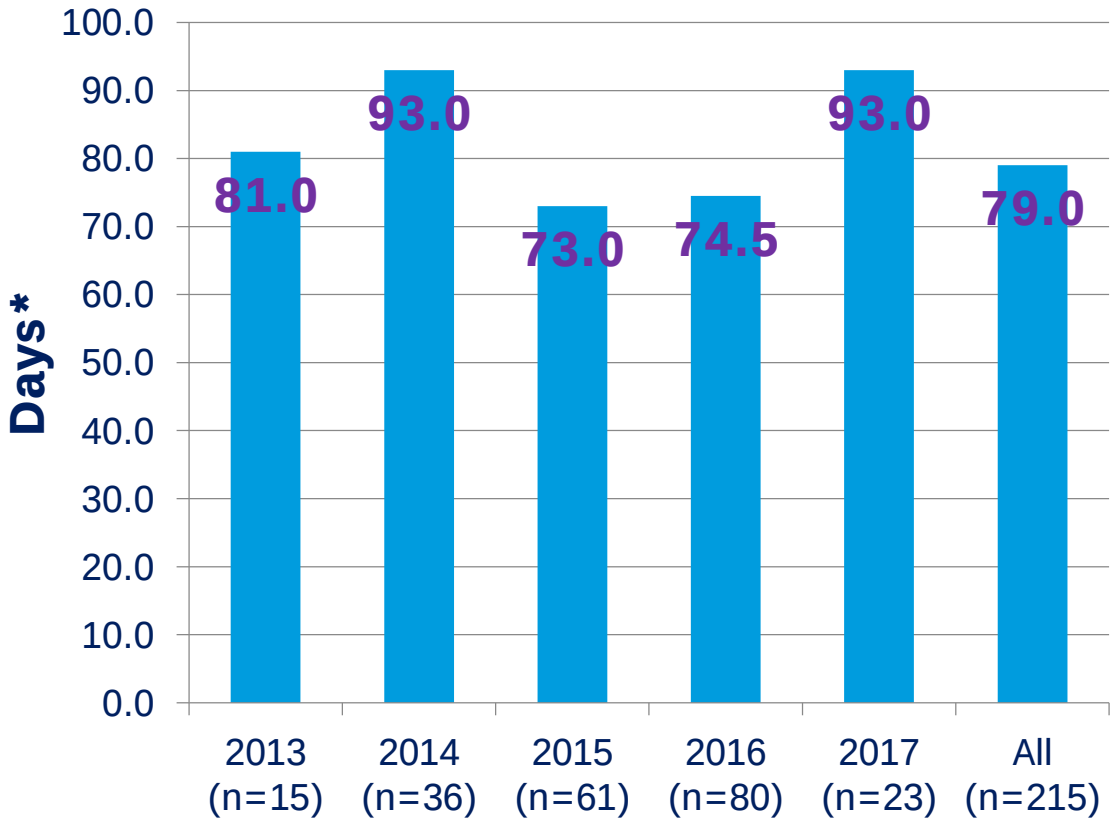
WHO PQ Collaborative Registration Procedure

Median time to registration

Days



*** Including regulatory time and applicant time**



As at 12 May 2017

Reliance among Regulators

Lessons learned

Reliance and recognition does not mean:

- A loss of sovereignty
- A loss of jobs
- A loss of income

Reliance among Regulators

Lessons learned

- Maintaining the sovereignty of countries to assess and approve medicines
- Must have trust in the reference regulator - Getting to know each other
- Overcoming issues of confidentiality of information
- Make sure all stakeholders are on-board and have the same information – familiarity with procedure and the role each party plays.
- Availability of reports/information to support the NRAs decision making process
- Ensure there are suitable processes in place within the NRA that support the reliance process
- Dedicated resources and priority within the agency for reliance process.

Section introduction

Building relationships between regulators

Building relationships between regulators

Trust in:

- Procedures and oversight
- Technical outcomes
- People

WHO Good regulatory practices guideline: Guidelines for national regulatory authorities for medical products

Finding a suitable Regulator

- ICH?, PIC/s?
- WHO Global Benchmarking Tool

Building relationships between regulators

WHO Regulatory Benchmarking Tool

WHO has been benchmarking and working with member states to strengthen regulatory systems since 1997

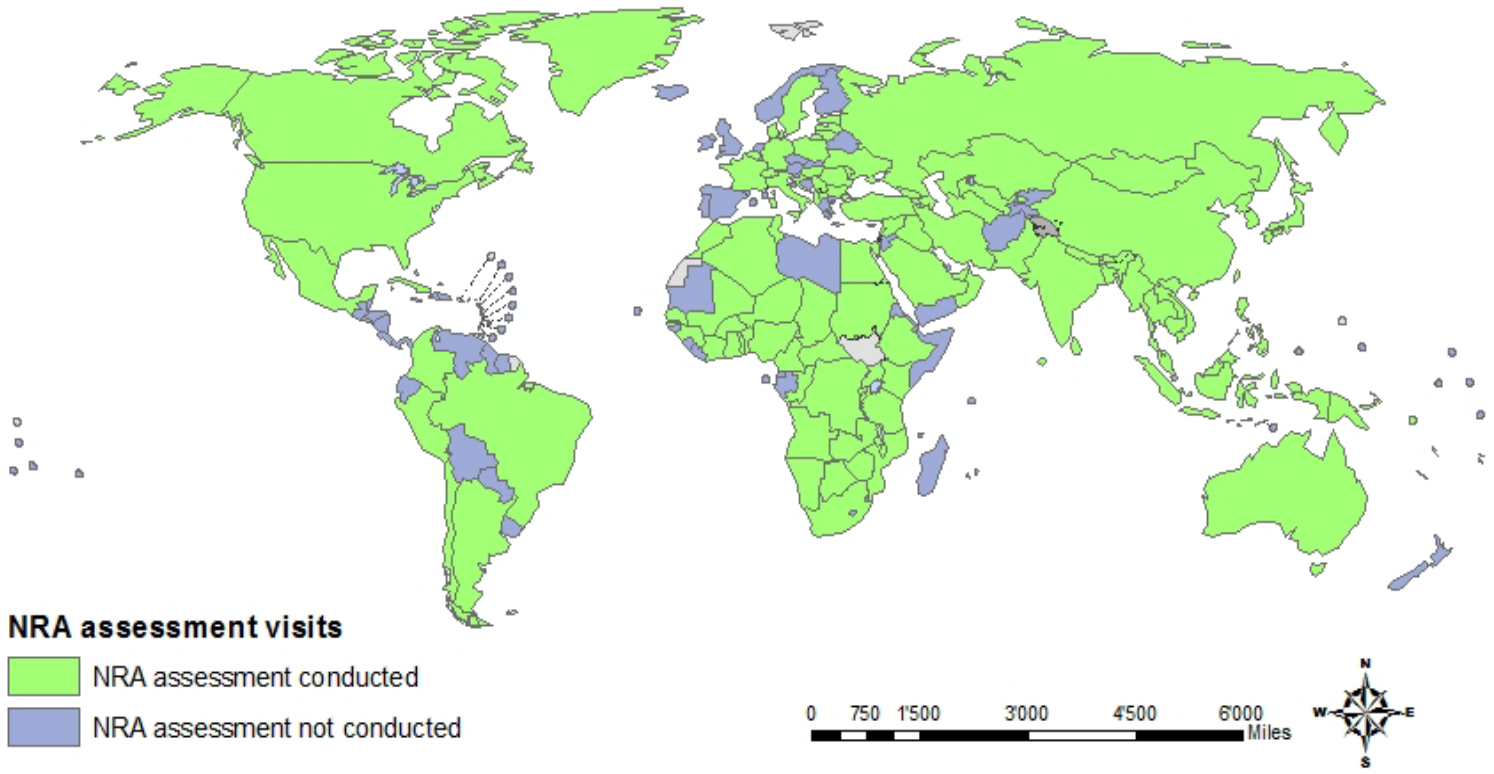
Goals:

- Strengthen regulatory systems to a level that represents a well-functioning, stable system, and
- Promote regulatory cooperation, convergence, networking, work-sharing and reliance

A regulator need not be a reference for every type of product, or every type of activity.

The benchmarking tool is aiming to provide regulators with information to enable collaboration.

WHO Global Benchmarking Tool



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Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.
Data Source: World Health Organization, Immunization Vaccines and Biologicals (IVB). Updated as of 5 June 2013
Map Production: Public Health Information and Geographic Information Systems (GIS)
World Health Organization in collaboration with P&B CONSULTING

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WHO Global Benchmarking Tool

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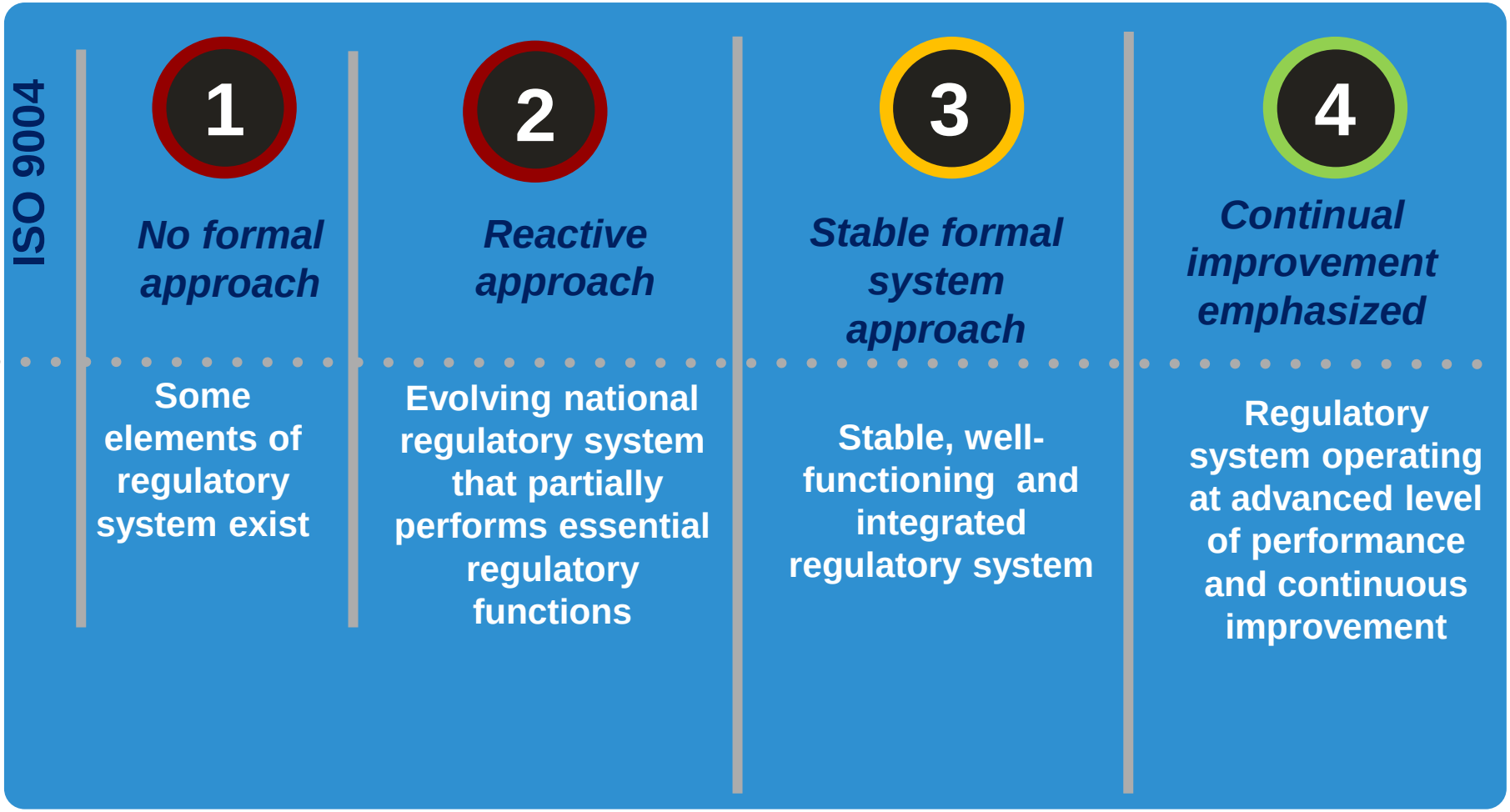
Maturity Levels



Building relationships between regulators

Its all about people

Trust cannot simply be mandated from on-high. It will require regulators to work together to establish a relationship

Establishing trust between regulators is a prerequisite to reliance and recognition.

RHT's success with the CRP relies in large part to work with:

- EAC Regulators - East African Community
- SADC Regulators - Southern African Development Community

Via:

- Trainings and interventions
- Attendance at PQT assessment sessions
- Use of PQT rotational positions

Looking forward

Harmonization, Reliance and recognition is well underway

To move forward regulators must recognise this as a legitimate alternative to inward focused regulation

There must be political willingness to undertake these activities.

Reliance and Recognition must move from being “side projects”

Procedures require integration, resources, it needs to be practised.

There are probably still several key technical barriers preventing maximum benefit

WHO are playing a catalytic role in global reliance

Many Thanks!

World Health Organization

Regulation of Medicines and other Health Technologies [RHT]

WHO

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