WHO Collaborative Registration Procedure for in vitro diagnostics

World Health Organization

Roundtable series: End to end diagnostics implementation; advocating for innovative solution

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All medical products should be approved by the national or regional authority before use

WHA Resolutions: WHA 67.20 (2014); WHA 67.21 (2014); WHA63.12 (2010)

How to “transfer/translate” the regulatory information to facilitate in-country approval?

WHO Prequalification provide good basis to facilitate national registration;

How do we get the prequalified products to the patients faster, and more efficient?

How do we ensure continued supply of safe products post-registration?

Rethink- Regulatory decision making

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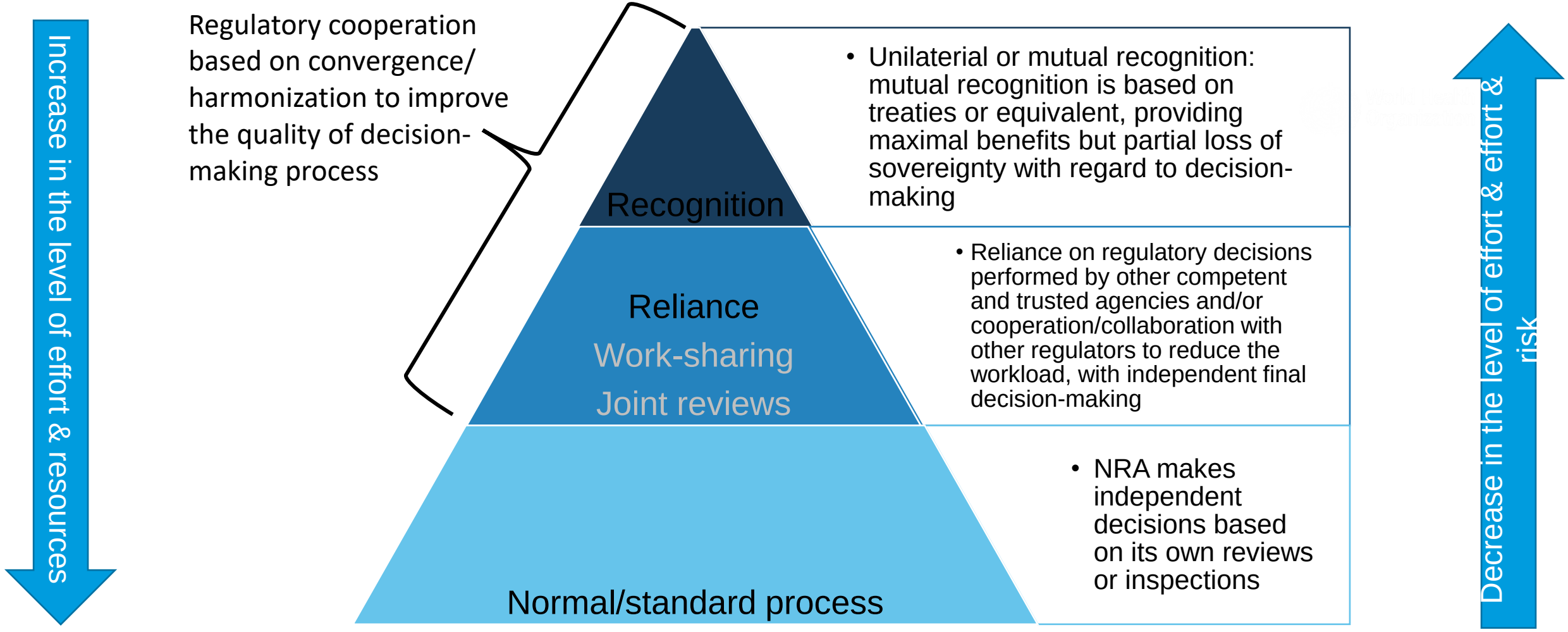

WHA resolution 67.20 (2014)

Options for regulators

- **Recognize (if outcomes are directly applicable to local context) =** Verify sameness
- **Reliance (if some outcomes are not directly transferrable / applicable to local context) =**
  - ✓ Abridged/abbreviated reviews
  - ✓ Organize R/B second review and inspections (desk assessments)
  - ✓ Consider in decision making
  - ✓ Use as quality assurance of national assessment and decision
- **Conclude differently from WHO PQ - justify**
- **Benefit from shared information for harmonization and training BUT**
- **Accelerate the national decision**

Facilitated pathways to “transfer” regulatory information & knowledge

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- Sharing information (assessment, audit and testing results) that serve as basis for national decisions – avoiding duplication.
- Voluntary participation – reference authorities, participating authorities and manufacturers/sponsors
- Sameness

PRINCIPLES

WHO collaborative procedure

Vaccines: 2004

Medicines: Started in 2012

Diagnostics: Pilot 2019

Vector control: Pilot 2020

Implemented for in vitro diagnostics

“SRA” collaborative procedure

Initiated in 2015

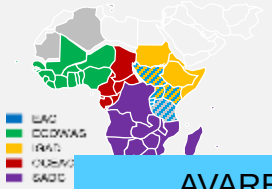
European Medicines Agency (EMA)

Medicines and Healthcare Products Regulatory Agency (MHRA)

20 African NRAs

Regional networks

African Medicines Regulatory Harmonization Project (AMRH)



AVAREF

ASEAN SIAHR Project

Caribbean Public Health Agency

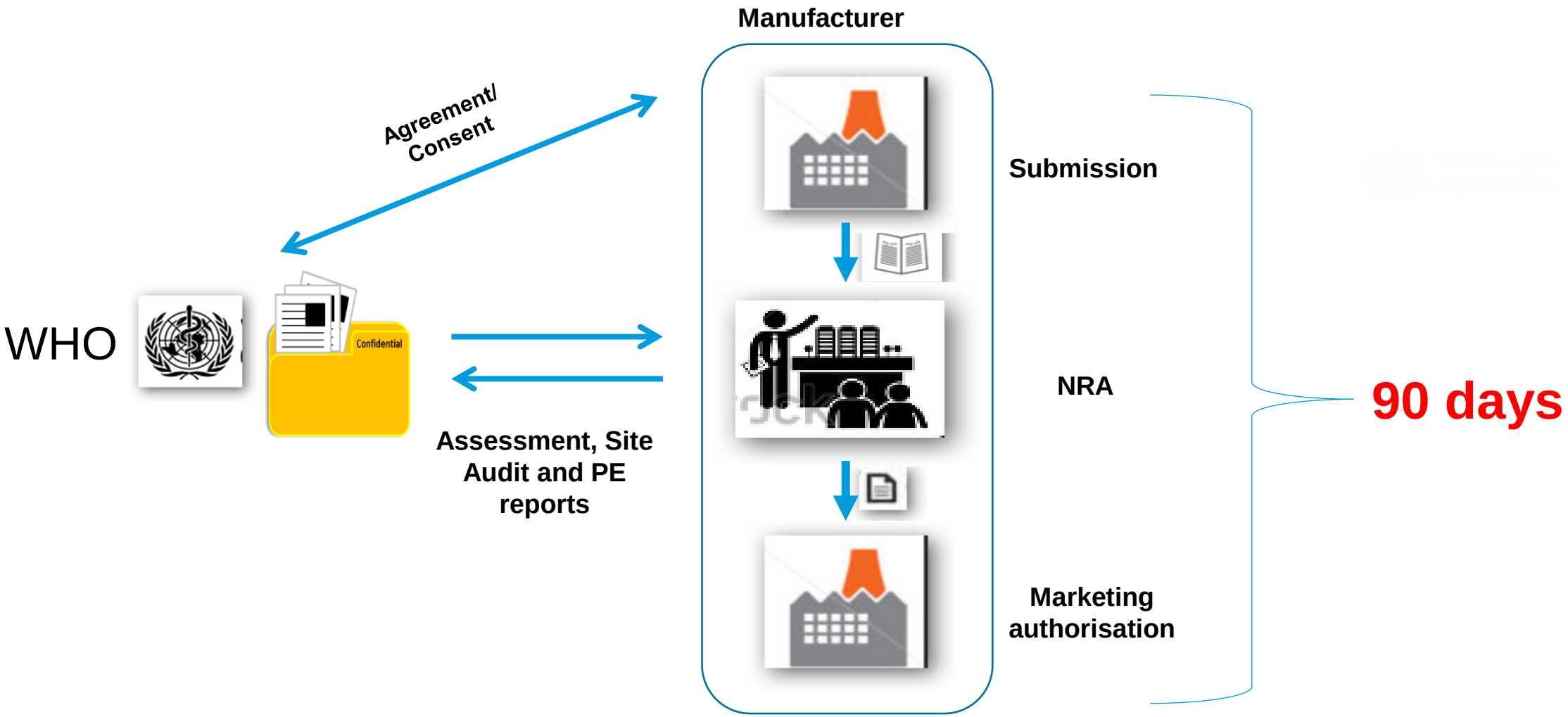
CARPHA

Not yet implemented for in vitro diagnostics

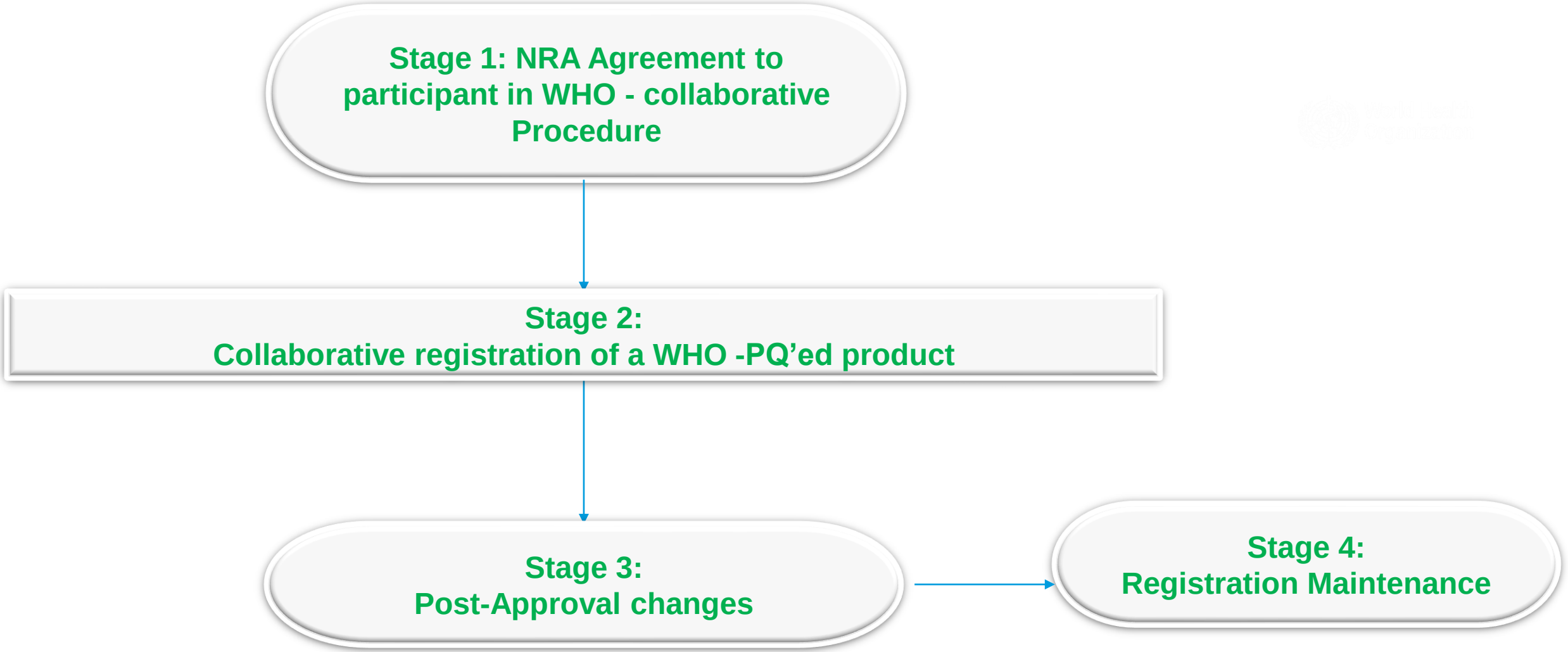
KEY Principles of CRP mechanism

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

How does the collaborative procedures works?



Key steps


Stage 1: NRA Agreement to participant in WHO - collaborative Procedure
Stage 2: Collaborative registration of a WHO -PQ'ed product
Stage 3: Post-Approval changes
Stage 4: Registration Maintenance

Pilot CRP for IVDs: April 2019 – Dec 2019

Objectives:

•Use the WHO-prequalification obtained for m-PIMA HIV-1/2 VL as a basis for country registrations.

•Assess feasibility of new WHO Collaborative Procedure including impact on registration timelines and requirements for additional country-specific studies.

Participating Countries:

Nigeria, Ivory Coast*, Tanzania, Ethiopia, Cameroon*. Upon Abbott request, Ghana was included in the pilot.

Results:

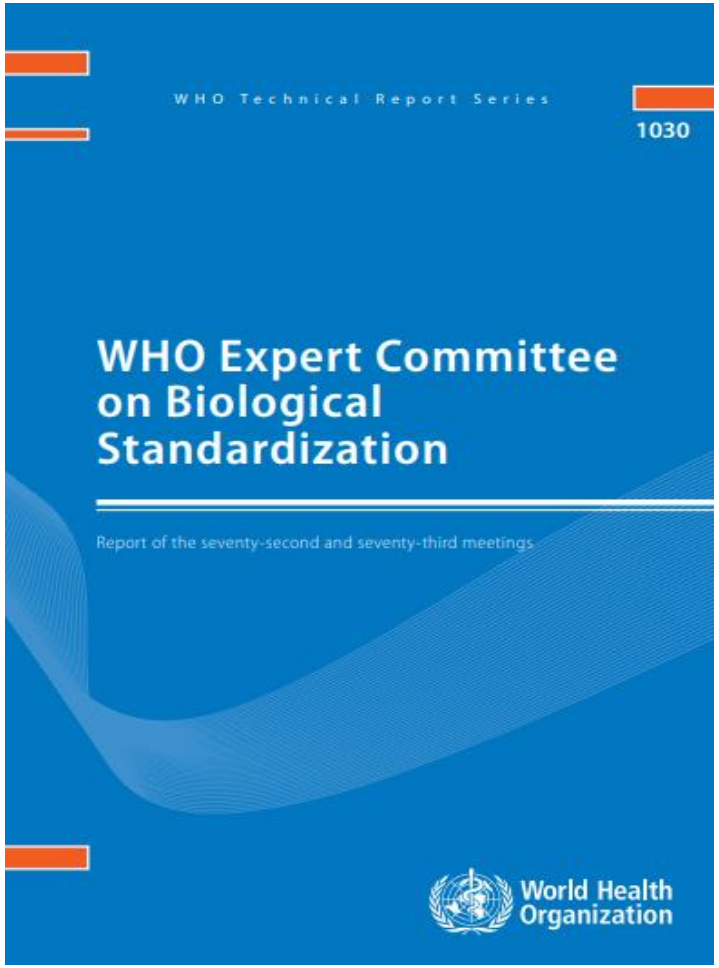
Three countries were able to register the products, Ivory Coast has not registered the product yet and *Cameroon did not participate*

Lessons learned

- Proved to be a great innovative mechanism that can accelerate registration of diagnostics and facilitate timely availability of IVDs. Benefits exhibited include:
  - shorter regulatory approval times. IVDs can be registered within the accelerated timeline of 90 days.
  - reduced workload for NRA experts due to reduced need for in-country evaluations based on acceptance of WHO PQ reports.
- Factors which contributed to delays include:
  - Inadequate capacity of the National Regulatory Authority experts especially in technical files assessment created unnecessary delays in processing and assessment of technical files.
  - In country registration requirements such as repetitive in country performance evaluation.
  - Inadequate communication between key participants.

Guideline published by ECBS- WHO Technical Series Report, 1030 in May 2021- Appendix 4

apps.who.int/iris/handle/10665/341239



Annex 4

Collaborative procedure between the World Health Organization and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified in vitro diagnostics

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Win-win outcomes for all concerned stakeholders

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, audits, performance evaluations;
- ✓ Accelerated and more predictable registration;
- ✓ Easier post-registration maintenance;

Procurers

- ✓ Time, assurance, availability.

Timely access to medical products – never-ending challenge

- ✓ Patients/consumers – wherever they are – deserve access to quality assured medical products with positive benefit-risk characteristics - UHC;
- ✓ Not a single regulator anymore can fulfil all regulatory work alone;
- ✓ Today's reality and demand: to generate quality national decisions regulators globally **MUST** collaborate and **MUST** take into consideration the information available from other regulatory authorities;
- ✓ Not using the outputs and outcomes from other regulatory authorities means lost opportunity, duplication of efforts, increased regulatory burden and waste of scarce resources.

Collaborative Registration Procedure (as well as other facilitated regulatory pathways) are critically important in helping to accelerate access to important medical products to the patients.

Thank you

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