Reliance and Collaborative Registration Procedure

Role of WHO Prequalification in facilitating Access to Quality-Assured Vaccines

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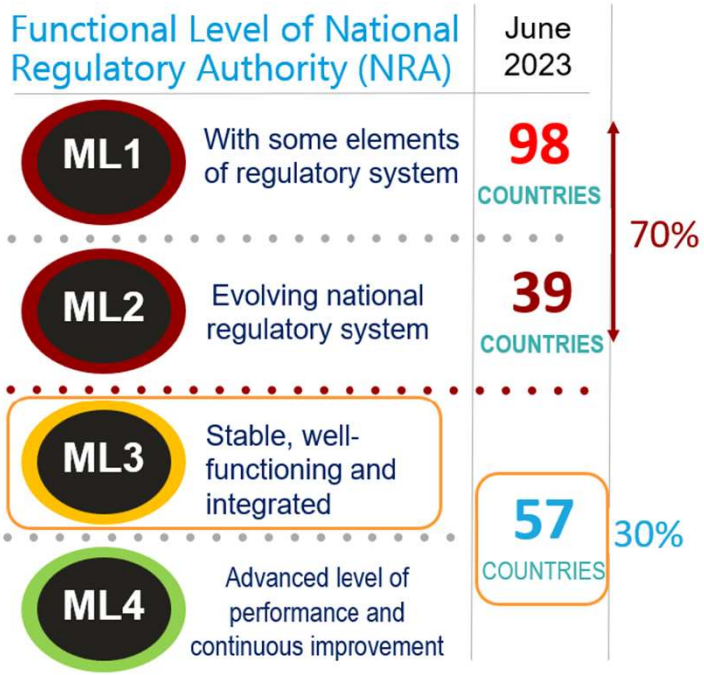
Why PQ and Reliance?



In 2022 alone, 6 countries achieved ML 3 or ML4

- **ML4 (med & vac): Republic of Korea**
- **ML4 (med): Singapore**
- **ML3 (vac): Egypt, China and South Africa**
- **ML3 (med): Nigeria**

Background:

- Over 70% of National regulatory authorities have inadequate regulatory functions

Facts

- 98 countries (51%) have limited capacity to perform core regulatory functions.
- Applicants face a landscape of disparate regulations, frequent delays and limited transparency.

This has implications on:

- Access to quality assured and safe medicines and vaccines in countries at ML 1 & 2 is not guaranteed:
  - high risk of Substandard and Falsified medical products
- Cost of inefficient regulatory systems drives up prices
- Regulators less prepared for public health emergencies

Prequalification: Product types and achievements

In vitro diagnostics (IVD) & male circumcision device (MCD)

- ✓ Cholera
- ✓ G6PD
- ✓ Glucose meter & Test strips
- ✓ Haemoglobin POC
- ✓ Hep B
- ✓ Hep C
- ✓ HIV/AIDS
- ✓ HPV
- ✓ Malaria
- ✓ Syphilis
- ✓ TB NAT

105 IVD | **1 MCD**

EUL:
- ✓ **Covid-19: 38**
- ✓ **Ebola: 6**
- ✓ **Zika: 4**

Finished pharma product (FPP), Active pharma ingredient (API), Quality control lab (QCL)

- ✓ BTP/SBPs (Cancer, Insulin)
- ✓ Child health
- ✓ Covid-19 (BTP, FPP, API)
- ✓ Diarrhoea
- ✓ Ebola virus disease (BTP)
- ✓ Hep B ✓ Hep C
- ✓ HIV/AIDS
- ✓ Influenza
- ✓ Malaria
- ✓ MDR bacterial infections
- ✓ New-born, young infants
- ✓ Neglected tropical diseases
- ✓ Nicotine replacement therapy
- ✓ Tuberculosis
- ✓ Reproductive Health

643 FPP | **161 API**

Including 11BTP & 15 SBP

57 QCL

Vaccines (Vx), Immunization device (ImD) & Cold chain equipment (CCE)

- ✓ 24 priority diseases, covering all vaccines required for routine immunization
- ✓ Covid-19
- ✓ Ebola virus disease
- ✓ Malaria

Eligibility criteria for evaluation includes:
- NRA functionality &
- Programmatic suitability

170 Vx | **EUL: 12 Vx**

421 ImD/CCE

Vector control products (VCP) & active ingredients

- ✓ Larvicides
- ✓ Insecticide treated nets
- ✓ Indoor residual spraying products
- ✓ Space spraying products
- ✓ Aircraft disinsection products

88 VCP

Inspection

- ✓ IVD
- ✓ Medicines: FPP, API
- ✓ BTP, SBP
- ✓ Vx
- ✓ ImD
- ✓ Clinical trials
- ✓ Bioequivalent studies
- ✓ Laboratories
- ✓ VCP
- ✓ Training

479 inspections in 2020-2022 despite COVID-19 pandemic

(*Current numbers of PQed/EULed products: March 2023)

Exhibit 32: Overview of major donors requiring PQ for procurement of vaccines

New compared to 2018

	Donor/ procurer perspective on PQ	Contingency approval process
Gavi The Vaccine Alliance	Only PQ accepted	Specific exemption to procure non-prequalified products possible under defined criteria
unicef supply	Only PQ accepted	-
Pan American Health Organization	PQ or SRA approval (PQ preferred)	Internal PAHO processes for the assurance of quality
MEDECINS SANS FRONTIERES	PQ or SRA approval or tFDA[1]	ERP[2] or MSF qualification process[3]
ICRC[4]	PQ or SRA approval	
International Coordinating Group (ICG) on Vaccine Provision[4]	PQ or SRA approval (PQ preferred)	Products listed under EUAL[5] or final written acceptance of product and manufacturer by the recipient country and WHO final procurement procedures

1. Tentative FDA 2 Expert Review Panel 3 Includes a preassessment based on product and manufacturer questionnaires, a Good Manufacturing Practices (GMP) of the manufacturing site, a product evaluation based on product and/or manufacturer questionnaire(s) according to standards set by WHO, and based on a standard Product Questionnaire common to the Interagency Pharmacist Group (UNICEF, ICRC, The Global Fund, WHO procurement center, UNFPA, GDF and MSF) and active monitoring and follow up 4 Details provided based on interviews with WHO colleagues / could not be validated with publicly available information 5 Emergency Use Assessment and Listing

Objectives/prerequisites of local production

- Local production of heath products should aim and be trusted to meet the following objectives/prerequisites:

1) Ensure quality/safety/efficacy.

2) Facilitate access.

3) Ensure sustainability.

World Health Organization

Definition of a WHO Listed Authority
Adopted by the ECSPP in October 2020, TRS 1033

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an

established benchmarking (GBT) AND a Performance Evaluation process

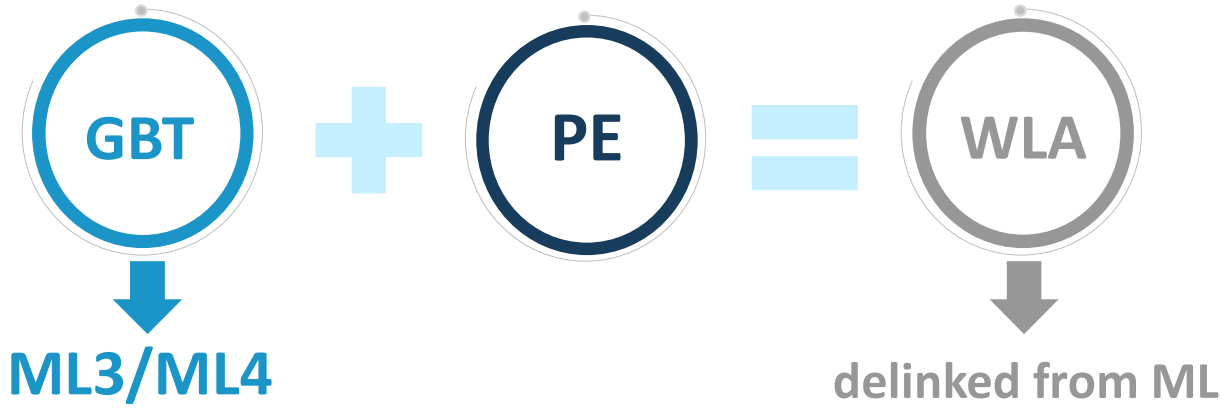
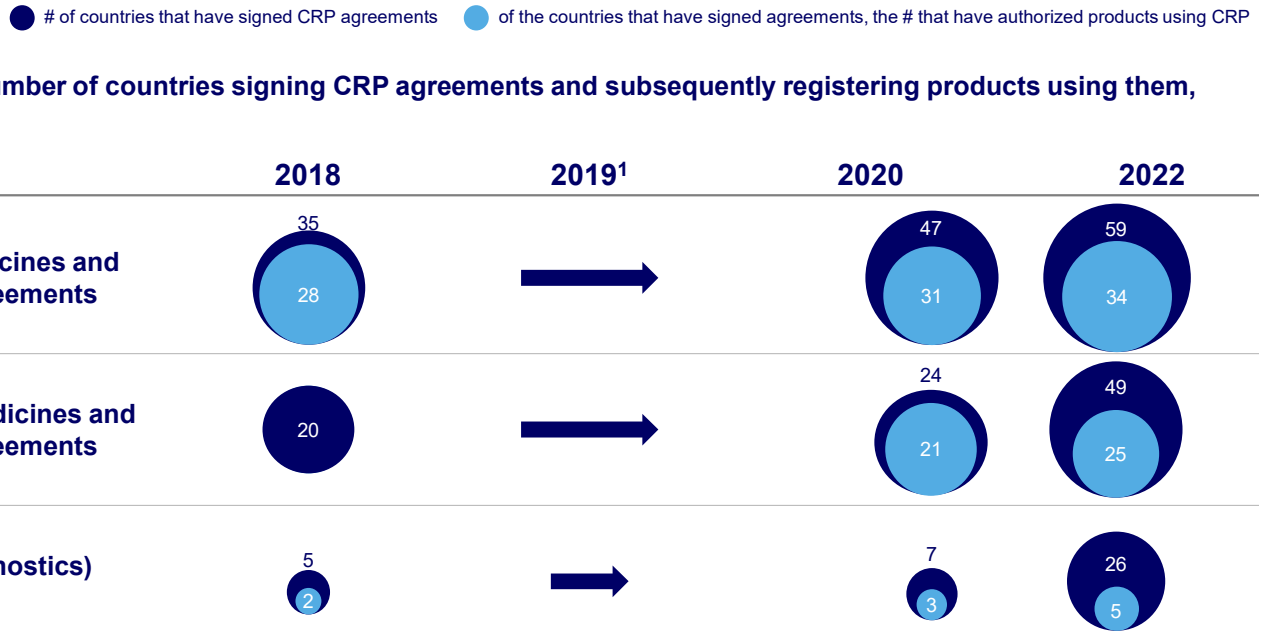
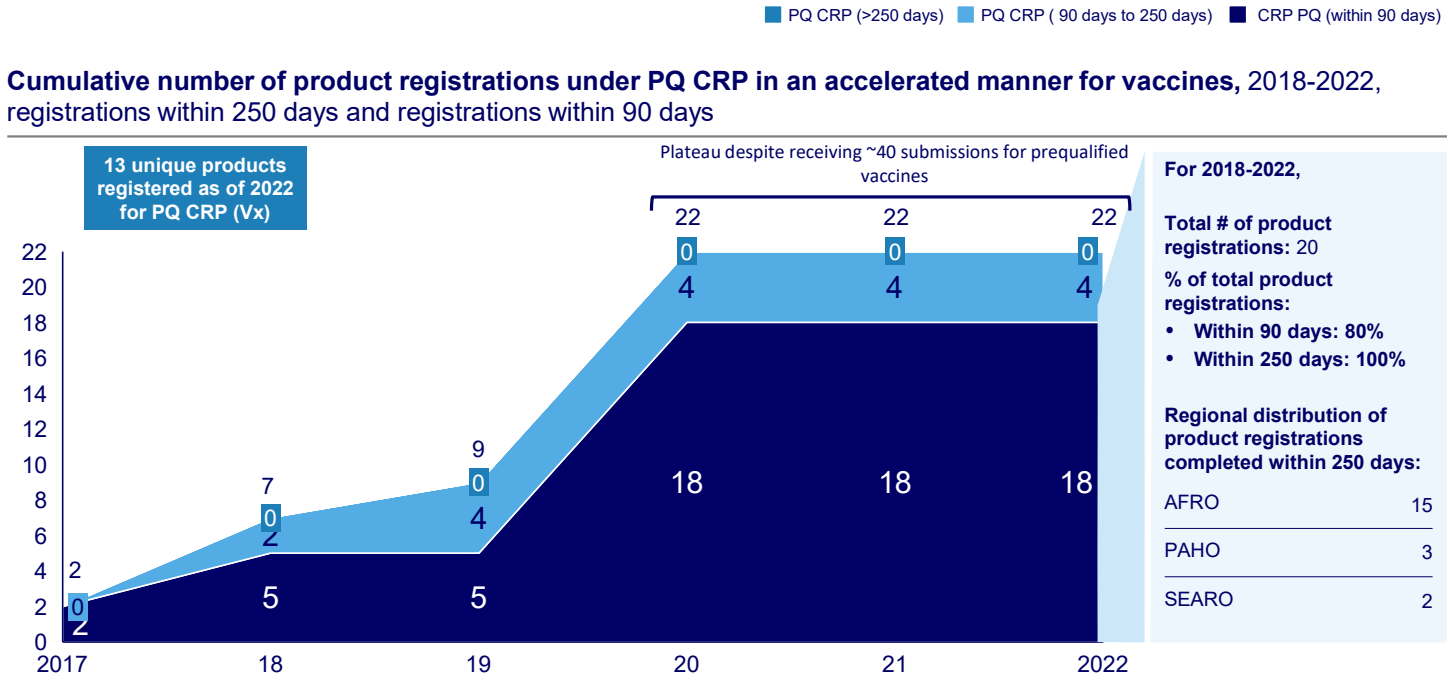


Exhibit 34: Number of countries that have signed PQ CRP agreements for vaccines and medicines and diagnostics, and SRA CRP agreements for vaccines and medicines between 2018 and 2022



1. PQ CRP for diagnostics started in 2019

Exhibit 37: Cumulative number of accelerated product registrations under PQ CRP for vaccines



Cumulative number of product registrations under PQ CRP in an accelerated manner for vaccines, 2018-2022, registrations within 250 days and registrations within 90 days

For 2018-2022,

Total # of product registrations: 20

% of total product registrations:

- **Within 90 days: 80%**
- **Within 250 days: 100%**

Regional distribution of product registrations completed within 250 days:

AFRO	15
PAHO	3
SEARO	2

RPQ- Prequalification

Summary of achievements

- **13% more products were prequalified in the last 5-year period** (2018-2022) compared to the previous 5-year period
  - If adjusted by removing COVID-19 products – the numbers are the same
- **EUL: 3x more products EUL-listed in the last 5-year period** (2018-2022) compared to the previous 5-year period, almost 100% of them are COVID-19 products

  # Number of IVDs listed in EUL

  Covid-19: **38**, Ebola: **6**, Zika: **4**

- For medicines, COVID-19 products were eligible for PQ - team was able to **establish a fast-track process to proceed them achieving median times far lesser than target**
- **Increase in the therapeutic areas within PQ scope** - five added for medicines[1], three for vaccines[2] and three for diagnostics[3]

Challenges

- **Limited human resources** – staff and external experts.
- Ever **increasing workload with expansion of PQ scope** without corresponding increase in resources.
- Competition for capacity of laboratories for PQ Performance Evaluation.
- **Backlog as the result of the impact of the pandemic** on PQ internal and external resources and on timely response of the applicants.
- **Immature regulation, harmonisation** and diverse stakeholders plus **legacy of old programmes** in certain product areas (VCPs and IVDs).

New activities and opportunities

- **New procedures (CSA, Parallel procedures for Guideline & PQ) and strengthened QMS** – better pipeline scanning, streamlining procedures, etc.
- **Implementation of the new IT system (ePQS)** will facilitate streamlining of workflow, transparency and reporting.
- **Recent independent RPQ impact assessment** – tool for advocacy and continuous improvement
- **Increasing number of WLAs** – will help PQT extend its reliance on the work of others NRAs and a bigger pool for experts.
- **Continued support and recognition** of the work of PQT by stakeholders, including member states, development partners, procurers and clinical departments, as a trusted symbol for safety, quality and efficacy.

CSA = Coordinated scientific advise, QMS = Quality Management System, WLA = WHO Listed Authorities

1. Infections in new-born and young infants and childhood pneumonia; Insulins and insulin analogues (BTPs); Certain cancers (BTPs); COVID-19 (BTPs and small molecules); Ebola Virus Disease (BTPs);
2. Ebola, Pneumonia, Malaria;
3. G6PD, Cholera, Syphilis, TB

Thank you for your attention

Siyabonga, Dankie, धन्यवाद, Asante

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