



Impact of WHO Prequalification and systems on access to Health

Developing countries vaccine manufacturers network

20th Annual General meeting

23 October 2019, Rio de Janeiro Brazil

Carmen Rodriguez Hernandez

Group lead Vaccines Prequalification



Overview

- WHO 5-year Action Plan to improve the quality and safety of health products
 - Regulatory systems strengthening activities
 - Prequalification and risk based assessment
 - Regulatory preparedness for public health emergencies

- Impact assessment of PQ

WHO Transformation

Major reorganization of WHO to deliver the mission and strategic priorities of the 13th General Programme of Work

Mission

- Promote Health
- Keep the World Safe
- Serve the Vulnerable

Strategic Priorities



“Together for a healthier world”

Dr Tedros Adhanom Ghebreyesus

13th General Programme of Work
2019-2023



Division: Medicines & Health Products

Health Products Policy and Standards

- Assistive technologies
- Blood Products
- Expert Committees
- INN
- Medical devices
- Pricing policy

Regulatory and Prequalification

- Regulatory Systems Strengthening
- Safety and vigilance related activities
- Prequalification
- Local production

WHO 5-year action plan to improve the quality and safety of health products



DELIVERING QUALITY-ASSURED MEDICAL PRODUCTS FOR ALL

2019–2023

WHO's five-year plan to help build effective and efficient regulatory systems



- Identifying the best ways to achieve a safe and quality-assured supply of medicines, vaccines and other health products for all
- Responding to the need for global health partners to work together towards a common goal
- Adopting a universal health coverage approach to reach the sustainable development goal
- Striving for better use of donor money and aid effectiveness by aligning milestones and activities among internal and external stakeholders

<https://www.who.int/medicines/news/2019/strong-reg-systems-to-reach-UHC/en/>

WHO 5-year action plan to improve the quality and safety of health products



**DELIVERING
QUALITY-ASSURED
MEDICAL PRODUCTS
FOR ALL**

2019–2023



WHO's five-year plan to help build effective and efficient regulatory systems

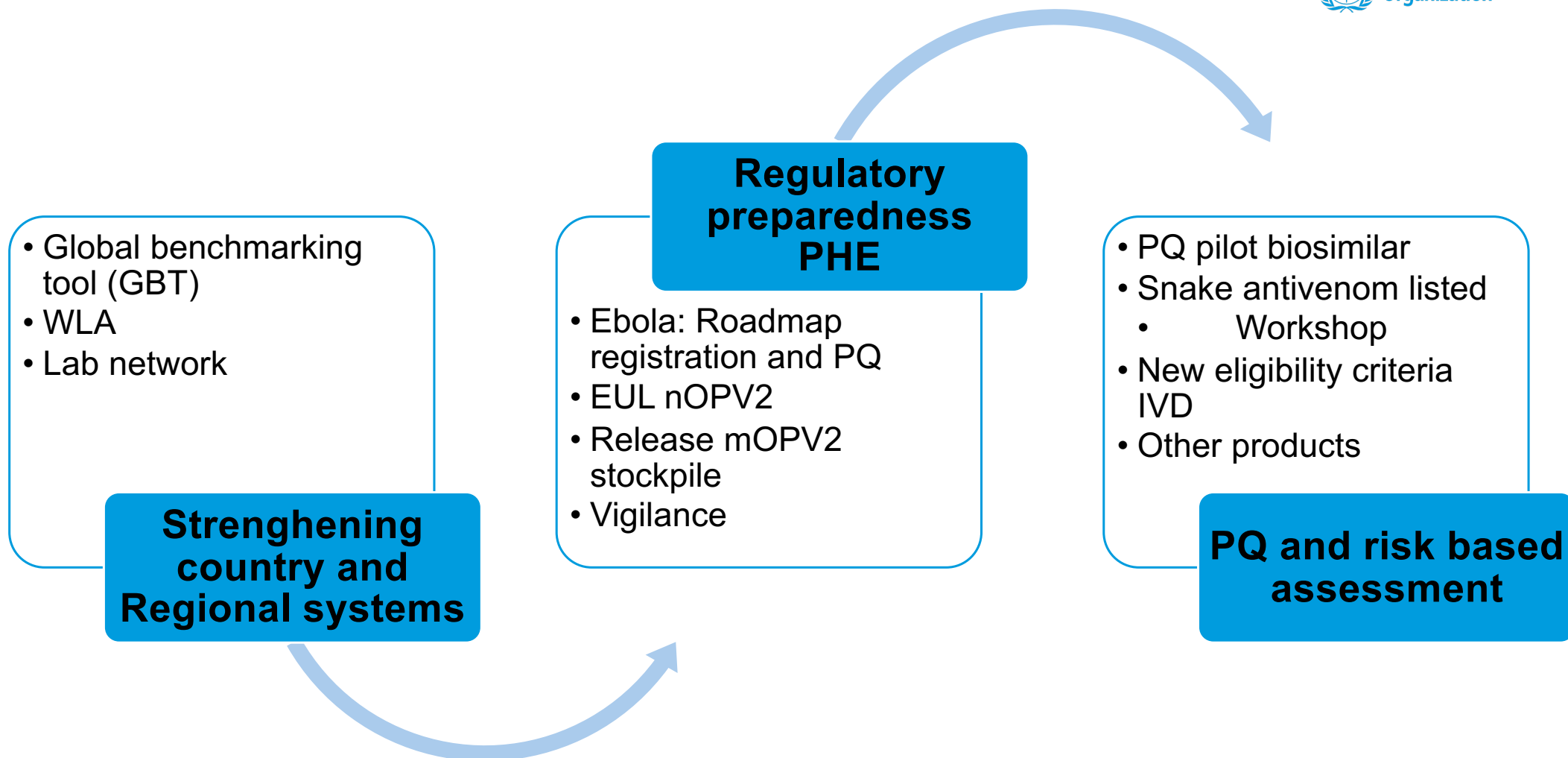


Four strategic priorities aligned with 13th GPW

- 1) Strengthen country and regional systems in line with the drive toward UHC
- 2) Increase regulatory preparedness for public health emergencies
- 3) Strengthen and expand WHO prequalification and product risk assessment processes
- 4) Increase the impact of WHO's Regulatory Supportive activities - efficiency, advocacy, knowledge sharing, joint planning

<https://www.who.int/medicines/news/2019/strong-reg-systems-to-reach-UHC/en/>

Strategic priorities GPW 13



Assessment pathways for vaccines and other biologicals

Prequalification (PQ)

- Response to the need of procurement agencies and Member States for quality-assured health products, by creating and applying quality-assurance mechanisms
- Reliance on “Stringent Regulatory Authority” possible

Risk based assessments time limited

- Licensed/PQ vaccine for emergency use (i.e fractional dose)
- Emergency use and assessment listing EUAL
- Stockpiles: smallpox and polio
- Snake antivenom
- Other products, i.e. DAT, TAT, Rabies, rsv mab

Snake antivenoms Risk benefit



- Public health snake bite/fatalities
- Time limited recommendation
- Further expansion to other regions/
further expansion of the scope of the
listing i.e PQ, is currently under
consideration. ➡ Roadmap

Lessons learned

Challenges for PQ while at the same time addressing the urgent need to devise a pathway for validating current products that might significantly reduce snakebite mortality and morbidity in Sub-Saharan Africa.

Highlighted number of areas in which support from WHO with recommendations for process and quality improvement can greatly improve the capacity of manufacturers to deliver antivenom products of high quality, improved safety and enhanced efficacy.



Regulatory preparedness: PQ of pandemic flu



- 1) Evaluate products profile to define assessment Prequalification pathway
- 2) Consultation with regulatory authorities (i.e USFDA and EMA experts) regarding evaluation and regulatory experience with the development of pre-pandemic vaccine candidates. Discuss a framework for a streamlined process
- 3) Conduct consultations with developers of pre-pandemic vaccines to estimate timelines for future submissions and initiate contact for pre-submission meetings

Mapping regulatory requirements: Emergency situation

What do countries
need?

What can be
waived/adapted?

What regulatory
approval?
Authorization for
use?

Import
requirements?

Regulatory preparedness: How?

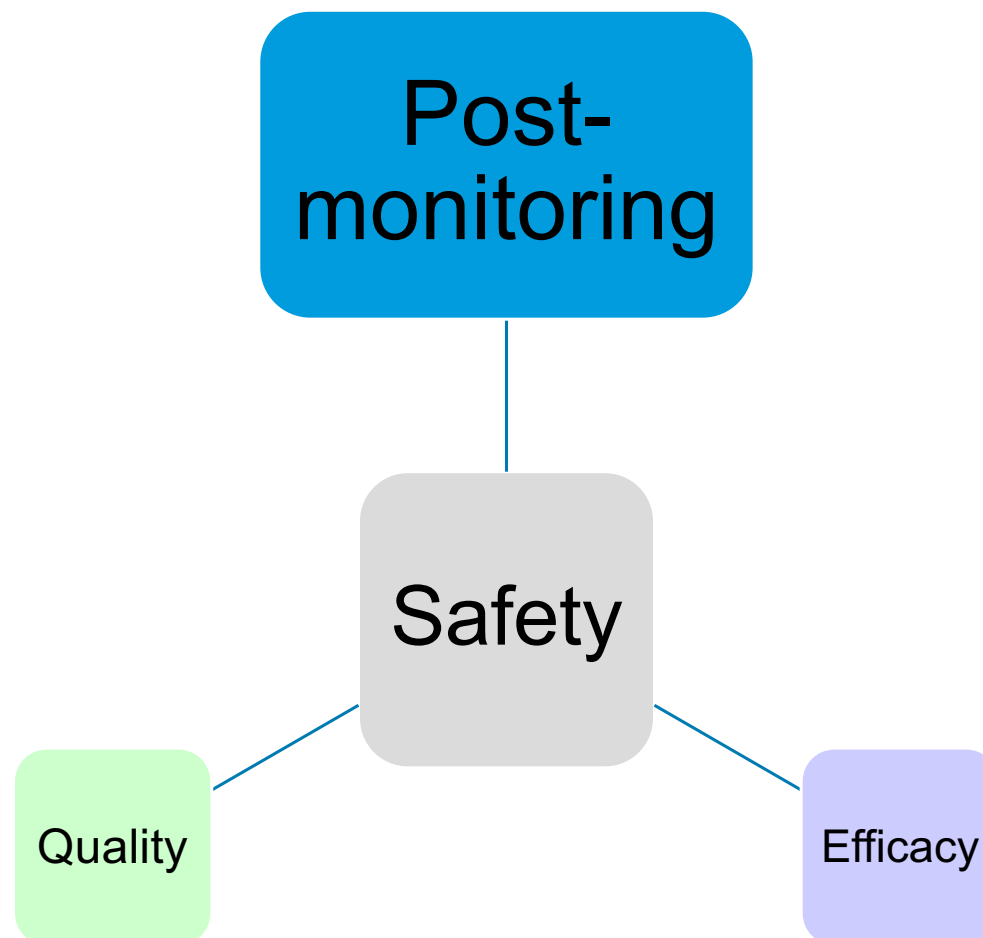
Member states

- Identification of “champions” NRAs

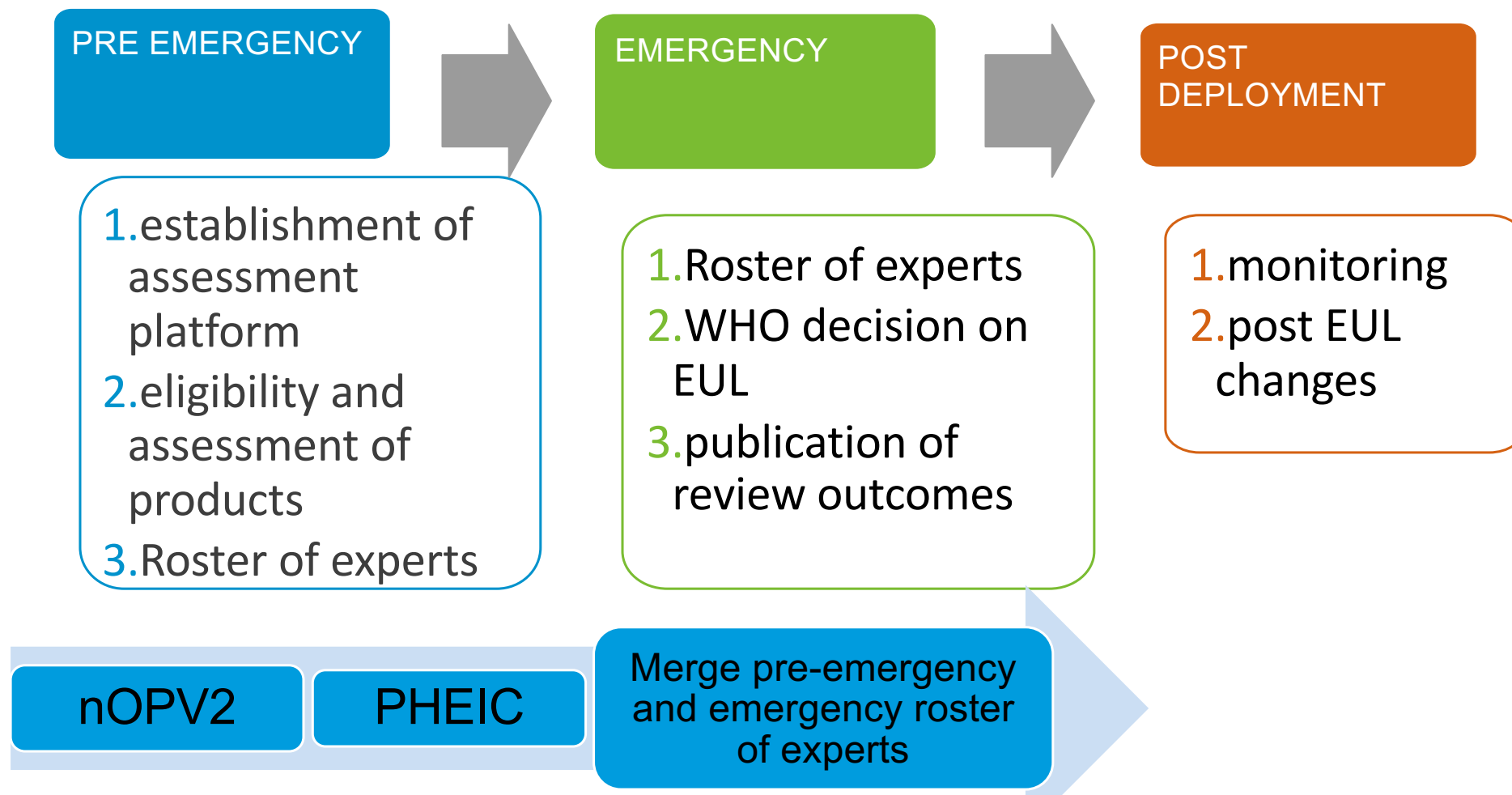
Partnerships

- Collaboration between relevant authorities in the region
- regulatory networks.
- Regulatory authorities overseeing emergency vaccines (ebola vaccine model)

Regulatory preparedness: What else?



EUL procedure for vaccines



Impact assessment: external evaluation



Impact Assessment of WHO Prequalification and Systems Supporting Activities

External Assessment Report on programmes
in the Department of Regulation of Medicines and other Health Technologies
June 2019



An external evaluation was conducted to increase a fact-based understanding of the impact and value of work on PQ of medicines, vaccines and in-vitro diagnostics and supporting regulatory activities, including norms and standards setting, regulatory systems strengthening, safety monitoring and vigilance

<https://www.who.int/medicines/news/2019/strong-reg-systems-to-reach-UHC/en/>

Some key findings

- PQ enables a core **market** of ~\$3.5 billion with the majority coming from vaccines
- WHO PQ has a Return on Investment of 30-40 to 1 (USD)
- Most donors and procurers and implementing partners view PQ approval as equivalent to SRA approvals
- 340-400 million more patients have access thanks to resources freed up by PQ
- NRA relying on CRP have achieved significant acceleration of approval timelines vs pre-CRP registrations

Impact assessment: opportunities for improvement

- PQ application process:
 - speed up response times
 - continue efforts to expand existing PQ-product list to an easily accessible database with a more end-to-end lifecycle view
- Increase awareness of WHO support provided during the early development phase of a product, in particular with LMIC manufacturers and NRAs
- Also specific “asks” for Norms and standards, GBT, etc.

Impact assessment: **Impact on countries**



- Since 1997, WHO trained more than 8000 NRA staff worldwide and number of functional NRAs increased by 70%
- Four types of inspection-related capacity building activities are held to support local NRAs
- Positive correlation between the number of substandard and falsified medical products reported and the number of trained focal points

Impact assessment: opportunities for improvement

- External communication and operational efficiency
- Cross-functional collaboration and communication, developing cross-functional / cross-stream teams – improve regular exchange of information and knowledge
- Increase cooperation with entities outside of RHT e.g. Emergencies, procurement

Impact assessment: **Impact on countries**



- Increased number of reports on adverse events in medicines increased in regions with extensive training activities
- Increased number of countries with basic vaccine safety monitoring system, with workshops held in the regions

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 collaboration with DCVMN**
- “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

Regulatory Action Plan 2019-2023

Vision **Strategic** **Collaboration** **KPIs** **Efficiency** **Priority** **Public Health** **Emergency** **Regulation** **Health** **Prequalification** **Impact** **Partnership** **Goals** **Quality** **Quality Assurance** **Safety** **Regulatory Systems** **Innovative** **GBT** **Reach the people** **Universal Health Coverage** **Quality-Assured Medical Products** **Reliance** **Global Standards** **Training** **Norms** **Actions** **Effective** **Vigilance** **Access**



thank you for
your attention

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.