

# The PQ (vaccines assessment) process mission, vision, objectives and stakeholders

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WHO PREQUALIFICATION PROGRAMME



# Outline

- Concept of vaccine regulation
- Prequalification
- Mission, vision and objectives
- Stakeholders
- Restructuration

# WHO Goal for vaccines regulation

Ensure that "100%" of vaccines used in all national immunization programmes are of assured quality

## Definition of "Vaccines of Assured quality"

- ✓ **National Regulatory Authority (NRA) independent from vaccine manufacturer & procurement system**
- ✓ **NRA is functional (*system + 6, 4 or 3 regulatory functions implemented*)**
- ✓ **No unresolved reported problem with vaccine**

WHO guidance by Experts Committee on Standardization of Biologicals (ECBS) recommendations on safety, efficacy and quality issued in WHO Technical Report Series (TRS)

# WHO Concept of Vaccine Regulation

## National Regulatory System : Governance

### + six regulatory functions

1. Marketing Authorization (MA) and Licensing Activities
2. Post-marketing activities including surveillance of Adverse Events Following Immunization (AEFI)
3. NRA Lot Release
4. Laboratory access
5. Regulatory Inspections
6. Authorization/Approval of Clinical Trials

## Required functions according to vaccine source

Vaccine Source		MAA & licensing	PMS	Lot release	Lab access	Regulatory Inspections	Authorization & monitoring CT
UN agency supply	<b>Regulatory System</b>			<b>Exporting country NRA+ V</b>			<b>All countries where CTs are performed</b>
Direct purchase						<b>Exporting NR</b>	
Producing country							



# WHO Concept of Vaccine Regulation

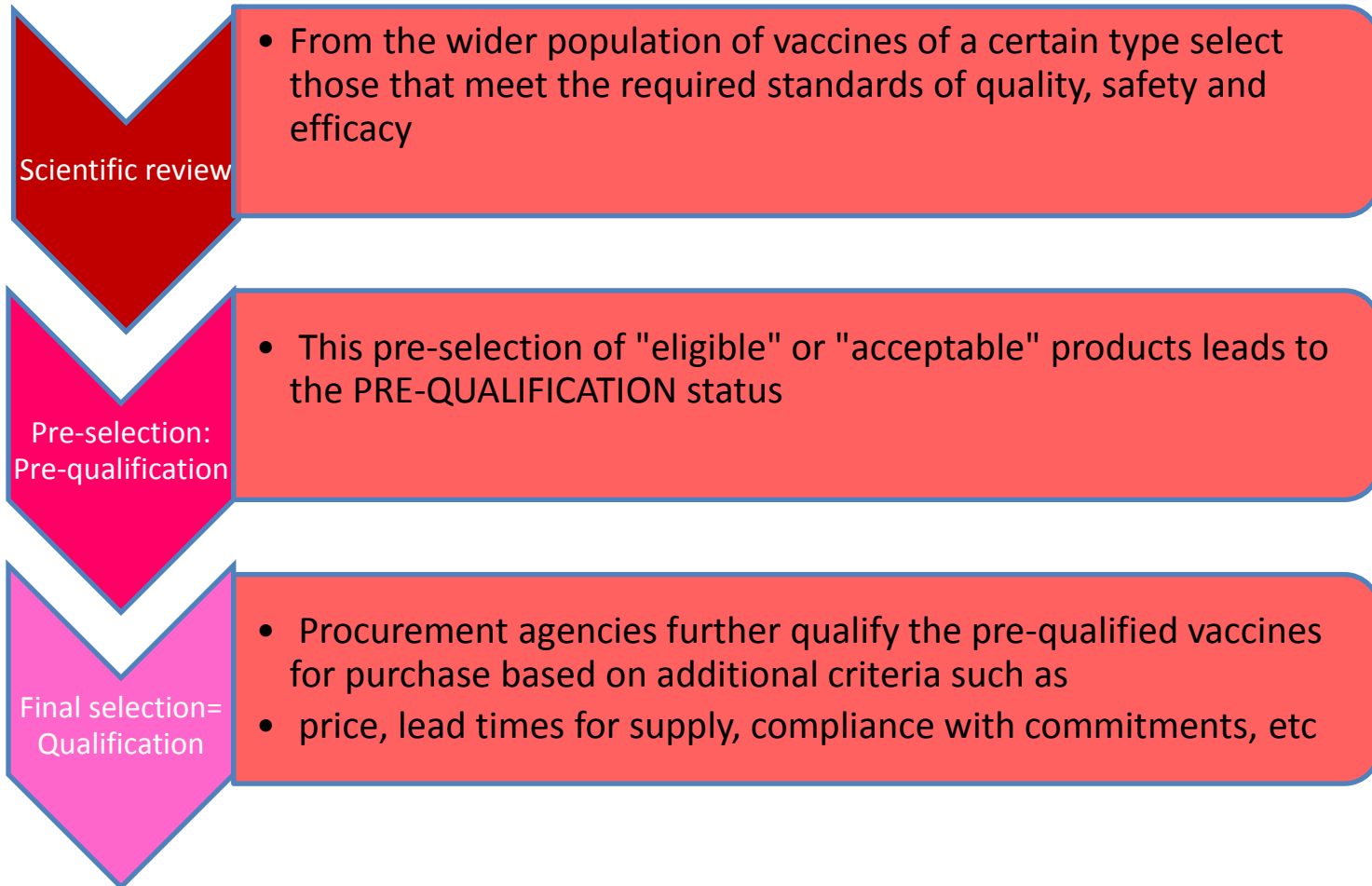
**Where does the Pre-qualification term come from?**

**What does it mean?**

**It is a procurement term**

**It means limiting a global public tender to fewer than the total universe of possible suppliers.**

# Prequalification



## Prequalification Team Mission

**Facilitate access to adequate supply of high quality vaccines to member countries**



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# Means to accomplish the mission



Provide advice to UN agencies on the quality, safety and efficacy of vaccines for purchase

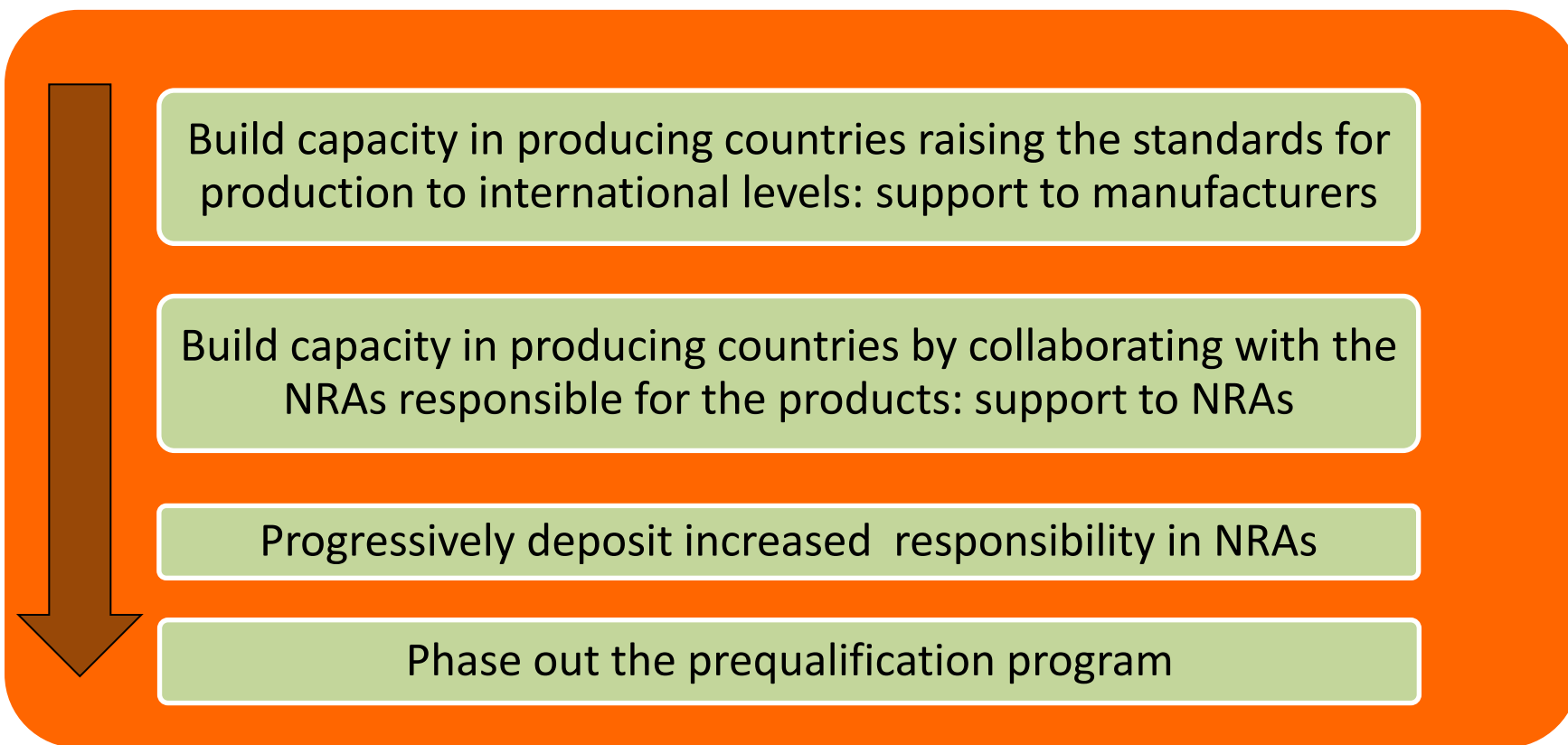


By assessing the acceptability, in principle, of vaccines for purchase by United Nations Agencies: Vaccines Prequalification Program



By continuous monitoring of quality and compliance with the established specifications

## Vision



# Objectives of the Vaccines PQ program

## MAIN

**Ensure supply of vaccines of assured Quality through UN agencies**

**Vaccines supplied meet WHO Recommendations issued by ECBS for quality, safety and efficacy and UN Tender specifications**

**Vaccines supplied meet the needs of the NIPs (programmatically suitable, compatible with the current immunization schedules)**

## SECONDARY

**Replaces regulatory oversight in receiving countries except for Marketing authorization and post-marketing surveillance**

**Used as a reference of quality by many countries that procure vaccines directly**

**Secure the supply base for vaccines by exploring alternative/additional sources**



## Prequalification Stakeholders

- ☐ Manufacturers and manufacturers' associations
- ☐ NRAs in producing countries and NRAs in receiving countries
- ☐ UN purchasing agencies
- ☐ GAVI
- ☐ Other purchasing agencies (MSF, DANIDA, JICS)
- ☐ Countries procuring vaccines directly
- ☐ Donors
- ☐ Immunization programmes
- ☐ Programmes for vaccine preventable diseases



# PQ restructuring



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# Role of WHO prequalification

- Facilitate access to safe, appropriate priority diagnostics, medicines & vaccines
- Support two of WHO's six core functions:
  - setting norms & standard/promoting their implementation
  - providing technical support, catalysing change & building institutional capacity.
- Contribute to achieving four of WHO's impact goals:
  - reduce under-five mortality
  - reduce maternal mortality
  - reduce the number of people dying from AIDS, tuberculosis and malaria
  - eradicate polio.



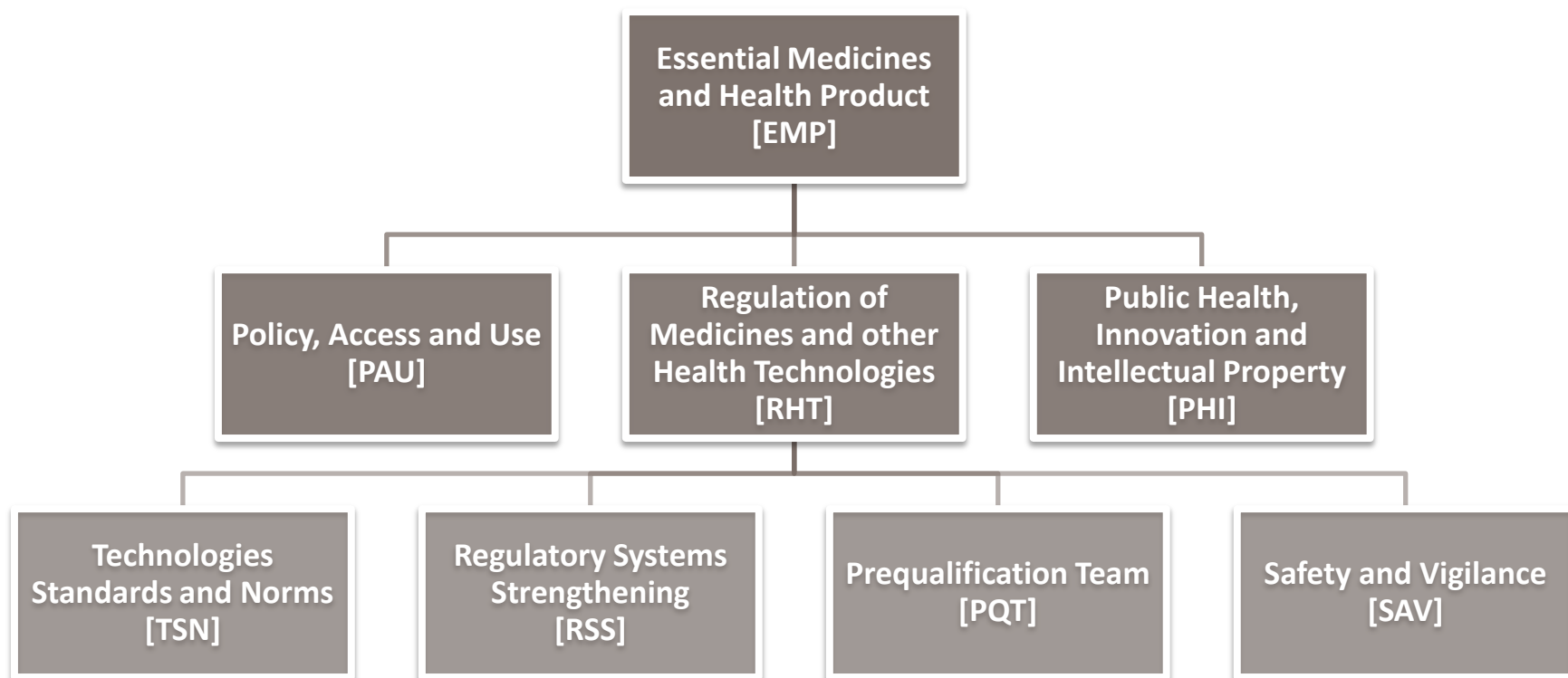
# Reorganization: single PQ programme for further impact & restructured regulatory units

Consolidated prequalification programme aiming at:

- **Enhanced management & operations**
    - e.g. quality management system
    - e.g. administrative efficiencies, incl. financial management
  - **Better relationship with stakeholders**
    - e.g. single voice when dealing with national regulatory authorities
    - e.g. increased transparency around processes and outcomes
  - **Cross-product stream learning**
    - e.g. **extension of ERP process to new product categories**
    - e.g. **bigger pool of external experts and testing laboratories**
    - **e.g. PQDx benefit from medicines and vaccines experience to improve efficiency**
    - **Flexibility**
      - transition business-as-usual PQ activities to NRAs
      - WHO PQ moves into new therapeutic areas (e.g. non-communicable diseases) and/or new product types (e.g. biologicals)
- Improved regulatory support — pharmacovigilance, norms & standards  
—to PQ processes

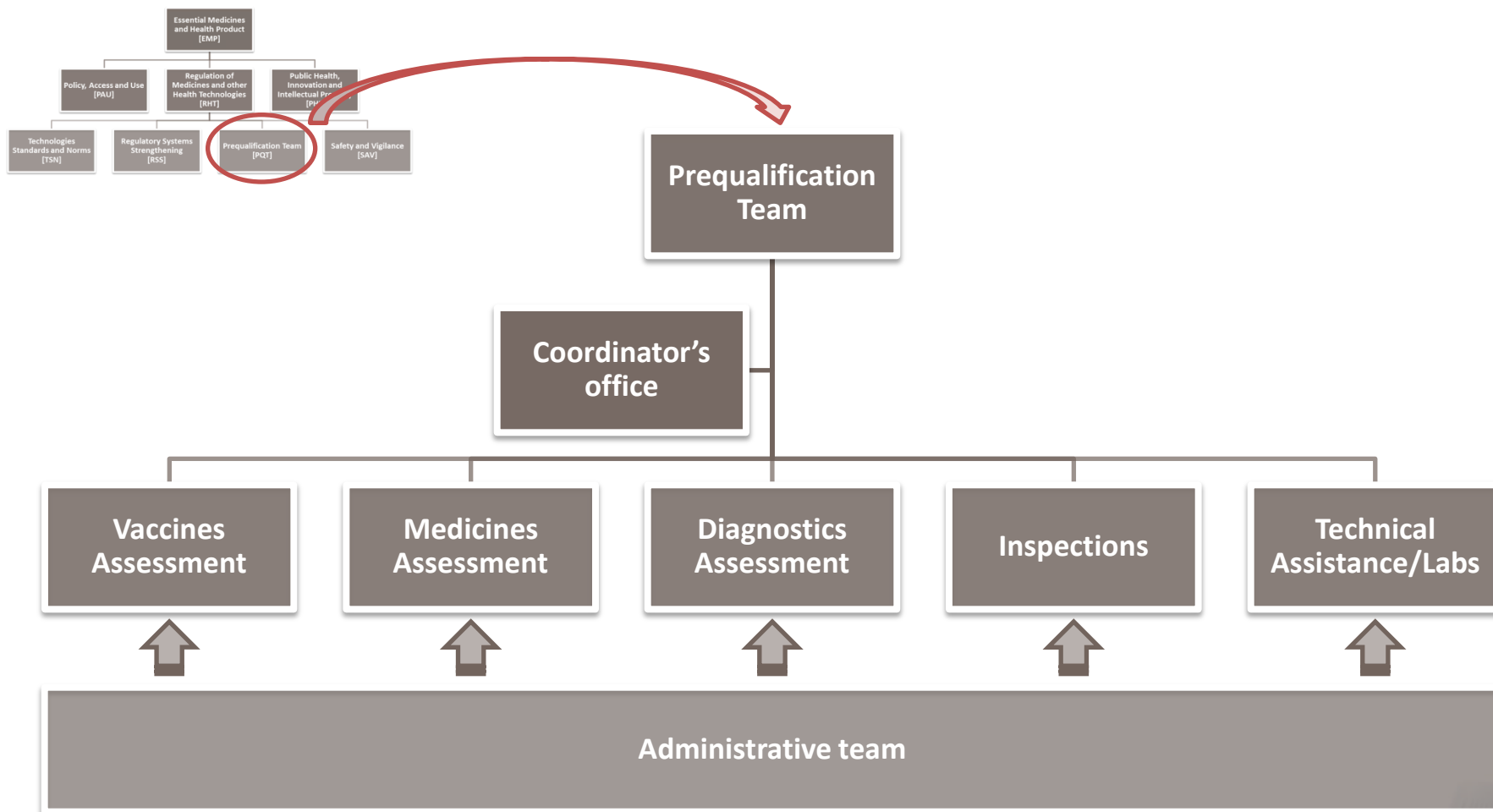


# Structure of Department of Essential Medicines & Health Products





# Structure of the Prequalification Team



# Thank You



[http://www.who.int/immunization\\_standards/vaccine\\_quality/pq\\_system/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/pq_system/en/index.html)

