WTO Technical Workshop on Covid-19 Vx R&D, Manufacturing and Distribution
11 February 2022: 13:00-15:00 CET

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Regulation and Prequalification (RPQ)

Quality Assured & Equitable

Organizational (Structure & Processes), Operational (HR, Funding Tools)
RPQ Strategic priorities:

1. SP 1: Strengthen country and regional regulatory systems
2. SP 2: Improve regulatory preparedness for public health emergencies
3. SP 3: Reinforce and expand WHO prequalification and product risk assessment
4. SP 4: Increase the impact of WHO regulatory support activities
## Features of PQ and EUL

### Prequalification (PQ) 1987
- Review of extensive quality, safety and efficacy and PSPQ for international supply
- Assessment performed by WHO independent experts
- Reliance on WHO Listed Authority (WLA) - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
- Pre-submission meetings encouraged
- Post-PQ monitoring
- Reassessment/requalification

### Emergency Use Listing (EUL) 2015
- Risk benefit assessment of essential set of quality, safety and efficacy data for use during PHEs
- Rolling review of data
- Assessment performed by WHO independent experts in collaboration with National Regulatory Authorities (WLA)
- Reliance on WLA - abbreviated process under oversight of mature regulators (evaluation and oversight of programmatic aspects by WHO)
- Pre-submission meetings encouraged
- Post-deployment monitoring
- Time limited recommendation
- Development should continue for MA/PQ
WHO regulatory preparedness for COVID-19 vaccines

WHO released “Considerations for the assessment of COVID-19 vaccines” (2020)

WHO issued a call for Expressions of Interest for Emergency Use Listing of COVID-19 Vaccines (2020)

... aiming for timely regulatory process while maintaining high evaluation stds for EUL/PQ

Source: https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/WHO_Evaluation_Covid_Vaccine.pdf?ua=1
In-country expedited approval for use & post-listing monitoring: the WHO regulatory alignment roadmap*

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<td>• Global regulatory cooperation</td>
<td>• Manufacturers EOIs (Phase IIb/III &amp; approval by NRA/SRA in charge of oversight within 6 months &amp; compliance with criteria for assessment)</td>
<td>• Establishment of assessment pathway according to NRA/SRA in charge of oversight</td>
<td>• Approval granted by NRA/SRA in charge of oversight</td>
<td>• Implementation of strategies for safety, quality &amp; effectiveness monitoring</td>
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<td>• Establishment of strategies for expedited approval in participants &amp; post-listing monitoring</td>
<td>• Discussions on rolling submission procedure</td>
<td>• Establishment of Review Committee (NRA/SRA in charge of oversight &amp; regulators/reviewers from potential user participants)</td>
<td>• Advisory committee convened (post-listing commitment)</td>
<td>• Validity of listing based on new data generated</td>
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COVAX  EUL/PQ  NRA reliance on EUL/PQ

Facilitated access to countries

• Sharing of assessment/inspection reports/lot release with regional-designated country reps
• WHO-facilitated national approval process

* Roadmap for WHO Assessment of vaccine x during the COVID-19 Public Health Emergency
Emergency regulatory authorizations issued by >150 LMI countries/territories

**AZ (incl. SII)**
- 142 countries/territories
- 1470 regulatory clearance
- 8 DS sites
- 12 DP sites

**Janssen**
- 115 countries/territories
- 786 regulatory clearance
- 3 DS sites
- 7 DP sites

**Moderna**
- 77 countries/territories
- 500 regulatory clearance
- 2 DS sites
- 3 DP sites

**Pfizer**
- 156 countries/territories
- 299 regulatory clearance
- 4 DS sites
- 10 DP sites

**Sinopharm**
- 80 countries/territories
- 80 regulatory clearance
- 1 DS/DP site

**Sinovac**
- 61 countries/territories
- 90 regulatory clearance
- 1 DS/DP site

**Novavax**
- 34 countries/territories
- 34 regulatory clearance
- 1 DS/DP site

**Viral vector**

**mRNA**

**Inactivated**

**Protein subunit**

Update: as of 01 February 2022
Assessment, monitoring, and adjustments to variants is critical

TAG for SARS-CoV-2 Virus Evolution
is assessing its effect on transmission, disease severity, vaccines, therapeutics and diagnostics, and the effectiveness of PHSMs

Transmissibility
(relative to circulating variants)

Virulence
(ability to cause severe disease)

Ability to evade immune responses
(prior infection and vaccines & therapeutics)

The R&D Blueprint for Epidemics
is convening researchers to identify knowledge gaps, and studies needed to answer the most pressing questions. Omicron variant assays & animal models study tracker

The WG on vaccines TPPs
is reviewing current desirable and minimum criteria for vaccines.

WHO BioHub system
a reliable, safe, and transparent mechanism to voluntarily share novel biological materials

WG for Clinical Management Networks
is assessing impacts of VOCs on current vaccines and WHO Global Clinical Platform for COVID

The Joint Advisory Group on Therapeutics Prioritization
is analyzing the possible effects on treatment of hospitalized patients.

WG on outpatient platform trials
is reviewing trial designs and challenges

TAG for COVID-19 Vaccine Composition*
Is assessing impacts of VOCs on current vaccines and determining whether changes to the composition of vaccines are needed.


SAGE on Vaccines & Immunization
is reviewing data to develop evidence based recommendations on the vaccination policies and target populations.

Thousands of researchers around the world are contributing data and expertise to the deliberations
