

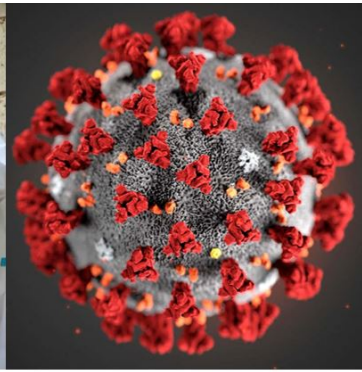

WHO Emergency Use Listing/Prequalification of COVID-19 Vaccines

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Emer Cooke Director - Department of Regulation and Prequalification
Access to Medicines and Health Products division




WHO preparedness activities for Covid 19 vaccines

Launch of the Expression of Interest (EOI) for candidate vaccines at latest stages of clinical development

https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/

Public consultation of “Considerations for the assessment of Covid 19 vaccines” – comments due by 8th October

https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/Link

Features of PQ and EUL

World Health Organization

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 Mature 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

Expression of Interest (EOI) for EUL/PQ
What does this mean in practice?

World Health Organization

- EUL/PQ - WHO led processes for advice on the quality, safety, efficacy and programmatic suitability, especially for LMIC supply.
- COVAX Advanced Marketing Commitment (AMC) can be based on Prequalification (PQ) or WHO Emergency Use Listing (EUL)
- Provides clear and transparent information for manufacturers for an evaluation by WHO.
- Enables end to end approach once efficacy is demonstrated.

An enabler for global access to COVID-19 vaccines to address the pandemic

Who can express interest to apply? (EOI)

Eligibility

Candidate vaccines

- **Phase IIb/Phase III**
- **Regulatory decision within 6 months**

Meet WHO Criteria

- Target product profile
- Norms and standards
- PQ/EUL

Alignment with policy recommendation (SAGE)

Part of WHO strategies to support access to COVID 19 vaccines

World Health Organization

Development of regional/global strategies

1. Involvement of regulators in review of applications submitted to WHO
2. Regional approach for expedited authorizations:
   - → Promotion of reliance principles in order to facilitate the decision making process
     - → sharing reports with all regulatory authorities

→ WHO member states have the sovereignty for decision-making

3. Regional strategy for post-listing monitoring.

Think out of the box, Unite, Collaborate & Cooperate

World Health Organization

What WHO is putting in place?

Global cooperation and coordination on regulation	Facilitation of authorization at global level	Mechanisms for 1. Review of data for emergency authorization and facilitation in other countries 2. Monitoring performance for quality, safety, efficacy and programmatic 3. Collaboration between MS

Path forward

- Pre-submission request opened immediately
- Extent of data and regulatory approvals will determine timelines and pathways
- Working in parallel on labelling, barcodes, safety monitoring, etc.
- Timelines will depend on read-out of sucessful phase III
- Independence of scientific review

Confidence on quality, safety and efficacy is key

Additional information EUL

Procedure and Questions and Answers

https://www.who.int/medicines/regulation/prequalification/prequal-vaccines/EUL_PQ_Vaccines/en/

Target product profile

https://www.who.int/docs/default-source/blue-print/who-target-product-profiles-for-covid-19-vaccines.pdf?sfvrsn=1d5da7ca_5&download=true

More information - EUL@who.int

World Health Organization

WHO/Otto B.

WORKING TOGETHER

Department of Regulation and Prequalification, WHO