EMERGENCY USE ASSESSMENT and LISTING PROCESS (EUAL) (Vaccines)
2014 Ebola crisis highlighted need for such an emergency process:

- Needed for UN procurement decision-making
- Needed for highly impacted countries in their regulatory decision-making
- Developed for three product streams currently in scope of WHO prequalification programme: Vaccines, pharmaceuticals and In-Vitro Diagnostics.
A rapid, time-limited procedure for the assessment of quality, safety and efficacy/performance during an outbreak, based on a minimal level of information, was established for vaccines, medicines and IVDs and published in July 2015.

The Listing provides guidance to UN procurement agencies, WHO product utilization advisory committees, national regulatory authorities (NRAs), and others involved in efforts to control an epidemic.

Principles of data requirements for each product type identified in the respective guidance document. Applicants are highly encouraged to contact WHO as early as possible to discuss specifics of their application.
EUAL - ELIGIBILITY

• Declared Public Health Emergency of International Concern (PHEIC) by the WHO Director-General
• Lack of routine marketing authorization of vaccines
• Vaccine manufactured in a country whose NRA has been assessed as functional for vaccine regulatory oversight by WHO.
• Vaccine manufactured in accordance with GMP standards
• Attestation from producer of intention to complete development and apply for WHO prequalification
• WHO may consider reviewing a candidate vaccine for EUAL that does not meet all of the above requirements
EUAL – CONTENT OF THE APPLICATION

- Submitted to and reviewed by WHO Prequalification Team – Vaccines
- **Manufacturing Quality Data**
  - Cell and seed bank characterisation
  - Justified methodologies and specifications
  - Process validation
  - Evidence of GMP compliance
  - Stability data
- Programmatic characteristics not acceptable for PQ may be allowed for EUAL
EUAL – CONTENT OF THE APPLICATION

• **Non-clinical Data**
  • Demonstrating acceptable safety, immunogenicity, and efficacy in the most appropriate animal model
    • If the non-clinical package is not complete at the time of submission, the applicant must submit adequate justification for the lack of complete data and a plan and timeline for submitting those data

• **Clinical data**
  • Demonstrating acceptable safety, immunogenicity, and efficacy, if available
    • If it is not possible to obtain efficacy data, the applicant will have to demonstrate that immunogenicity data are sufficient under the circumstances.

• A plan to monitor quality, safety, and efficacy in the field and to submit the new data as soon as possible to WHO.
WHO public report will be available on the WHO website.

The validity of a listing will generally be for 12 months.
- It could be reviewed and extended if necessary.
- It could be extended beyond the PHEIC (stockpile)

Decisions will also be reassessed if further data become available that could alter the original opinion.
EUAL: Ebola experience

• Rolling submissions

• Discussion on regulatory pathways with relevant authorities

• Facilitation of an expedited review process using the principles of collaborative procedure between WHO PQ and regulators from affected countries.

• Need for revision of EUAL
EUAL