

## WHO'S EMERGENCY USE LISTING PROCEDURE

WHO's Emergency Use Listing (EUL) procedure involves careful and rigorous assessment of available quality, safety and efficacy data to enable early, targeted use of yet to be licensed vaccines, treatments or diagnostics for response to a Public Health Emergency of International Concern.\*

## PREPAREDNESS PHASE

- Establish assessment platform for WHO, external experts and regulatory authorities to collaborate and assess a product
- Agree on essential requirements that a product must meet on quality, safety, and efficacy
- Determine if product is eligible for assessment under EUL

## **EMERGENCY PHASE**

- Conduct rigorous assessment of available data for the product to determine quality, safety and efficacy
- Review inspection reports for manufacturing and clinical trial sites, and as appropriate, carry out on-site inspections to ensure highest standards are met
- Issue recommendation on whether the product should be used for emergency response under EUL\*\*

## **POST-LISTING PHASE**

- Continue to collect and assess safety and efficacy/effectiveness data on the product's use under EUL
- Actively monitor product usage for adverse events and ensure that high quality standards are met
- Reassess validity of listing based on new data generated

- \* This simplified graphic highlights three sets of key actions that make up the EUL process. Depending on the emergency, there may be overlap between phase activities.
- \*\* For vaccines, the WHO Strategic Advisory Group of Experts (SAGE) on Immunization endorses policies and strategies for use.