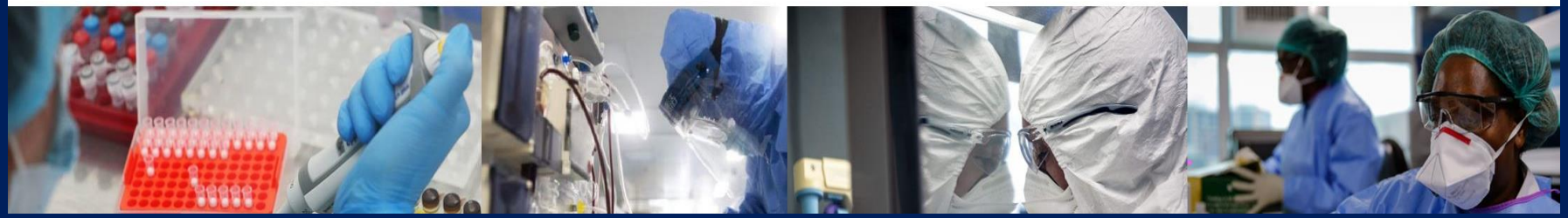
Prequalification of Rabies vaccine



Carmen Rodriguez Team Lead vaccines PQ
Regulation and Prequalification

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World Health Organization 75 HEALTH FOR ALL

Goal & objective

Goal: to optimize access & availability to safe, efficacious and quality-assured vaccines

Objective of this presentation:

- Provide an overview of WHO assessment processes
- Provide an overview of prequalification of rabies vaccines
- Path forward mRNA vaccines
- Challenges mRNA vaccines

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**

Prequalification process

- Scientific review of CMC dossier (Including PSPQ)
- Scientific review of clinical data (Including RMP)
- Testing of samples
- Consultation with responsible NRA
- Inspection to manufacturing facilities

PQ rabies vaccines

Manufacturer	Vaccine Presentation
Serum Institute of India Pvt. Ltd.	1 dose vial + 1 dose ampoule (diluent)
Chiron Behring Vaccines Private Ltd.	
Sanofi Pasteur	
Zydus Lifesciences Limited	

Path forward mRNA vaccines

- Vaccines should comply with PQ expectations
- Priority list for PQ
- Consideration for updated Norms and Standards and policy recommendations
- Licensed by benchmarked NRAs at least ML3
- Collaboration arrangements with authority of reference exercising regulatory oversight
- Programmatic suitability compliance

mRNA platform vaccine. General & Specific Challenges

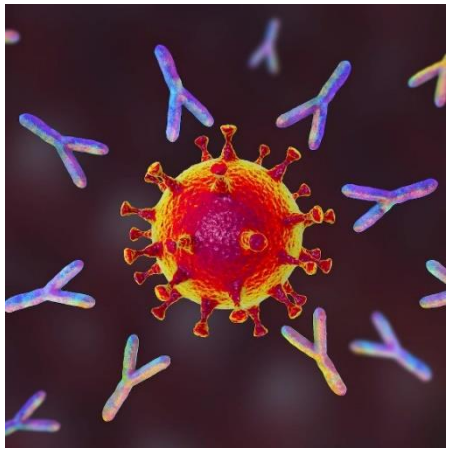
1. **Physical stress and agitation**:
   - Studies showed the potential impact on the Q-S-E of the vaccines.
   - In-land transportation and distribution
   - Management and monitoring of potency loss due to agitation in the field.
2. **Vaccines presented in multi-dose (>2 doses per vial)** should include an **antimicrobial preservative** and be in **compliance with the WHO MDV policy.**
3. **Current vaccines require controlled storage conditions below or at -20°C; even ultra-low cold chain (UCC) supply chain requirements.**
4. **Absence of VVM.**

Failure of mRNA-based and certain other vaccines to comply with PSPQ mandatory and critical characteristics.
This should not be ignored as these reflect the LMIC needs (clients/customers)

Key Takeaways

- mRNA-based vaccine has emerged as a rapid and versatile platform to quickly respond to PH challenges (e.g., COVID-19 pandemic).
- At the start-up, tech can be expensive (e.g., Mfg, QC).
- Minefield by an array of patents and rights.
- National regulatory framework: WHO TRSs, ICH guidelines.
- National Regulatory System (e.g., ML3).

THANK YOU FOR YOUR ATTENTION!!



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