Prequalification of Rabies vaccine

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Regulation and Prequalification

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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

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Vaccine Presentation</th>
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<tr>
<td>Serum Institute of India Pvt. Ltd.</td>
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<tr>
<td>Chiron Behring Vaccines Private Ltd.</td>
<td>1 dose vial + 1 dose ampoule (diluent)</td>
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<td>Sanofi Pasteur</td>
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<td>Zydus Lifesciences Limited</td>
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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!!