

Regulatory/PV Working Group Meeting with WHO SEARO February, 2026



DCVMN
INTERNATIONAL
Developing Countries Vaccine
Manufacturers Network International

Date: Feb 16-17, 2026

What We Are Proposing

MOVE FROM:

- Each NRA performing full independent review
- Redundant inspections
- Full lot testing in every country
- Different PAC classification
- Country specific Clinical trials

TO

- **SEARO reference-based interdependence and reliance on:**
 - Dossier Assessment
 - Inspection outcomes
 - Sample Testing
 - Agreed clinical relevance assessment
 - Pharmacovigilance
 - Post Approval Changes/Variations

Why This Works in SEARO

- Shared disease epidemiology
- Similar immunisation programs
- Comparable manufacturing exposure
- Increasing ML3 capability in the region
- Political acceptability higher than extra-regional reliance

The Target points:

GMP Inspection Recognition

- Accept WHO ML3 inspection outcome
- Risk-based verification only if triggered

Testing Rationalisation Pilot

- Move from full lot testing to:
 - Reduced panel
 - Periodic confirmatory testing
 - Reliance on WHO reference Labs

Abridged Review for WHO PQ / ML3-approved Vaccines

- Scope: Quality summary + benefit-risk summary + PV readiness
- No full module re-assessment
- Defined review clock

PAC Fast Lane (Criticality Assessment)

- DP site addition (with comparability approved by reference NRA)
- Minor process parameter optimisation
- Label updates without clinical impact

What WHO SEARO Can Enable

- Identify 1–2 willing ML3 reference authorities
- Convene technical exchange workshops
- Endorse pilot governance model
- Publish non-binding regional implementation note

NRA Capability Scale vs SEARO-DCVMN role on Regulatory reliance

- **Tier A (SEARO Reference-capable today):** ML3 vaccine systems listed by WHO → **India, Indonesia, Thailand**
- **Tier B (Transitional):** not ML3-listed for vaccines as of Dec 2025; can do partial review/verification depending on function
- **Tier C (Developing):** not ML3-listed for vaccines as of Dec 2025; limited capacity, often process/legal constraints dominate

WHO SEARO Role:

- Convenor
- Capability assessor
- Pilot facilitator
- Neutral technical bridge

DCVMN Role:

- Provide case studies
- Technical workshops
- Pilot participation
- Tool refinement

SEARO Regulatory Reliance: Functions, Challenges, and Capability Scale

Reliance Function	Current Challenges seen across SEARO	Typical NRA Objection
1) Dossier review (Quality + Clinical summary + local relevance)	Parallel full reviews, inconsistent questions, variable review clocks	“We must do a full national assessment” / “Need local relevance justification”
2) GMP inspection reliance (interdependence within SEARO)	Duplicate inspections, limited inspector availability, inconsistent acceptance of foreign/regional inspection outcomes	“We must inspect ourselves” / “We can’t rely on another country’s inspection”
3) Lot release / sample testing (QC lab dependence)	Local testing mandates delay supply; redundant test panels; lab capacity varies; import lot release bottlenecks	“National testing is legally required” / “We don’t trust CoA alone”
4) Post-Approval Changes (PAC) classification & timelines	Widely different major/minor classification; unclear doc expectations; unpredictable timelines; repeated data requests	“Every change must undergo full review” / “Our variation rules are different”

SEARO Regulatory Reliance: Functions, Challenges, and Capability Scale

Reliance Function	Current Challenges seen across SEARO	Typical NRA Objection (SEARO lens)
5) Clinical trial acceptance / bridging (routine + outbreak)	Pressure for local trials even when strong global data exists; ethics/operational constraints; outbreak urgency drives risk-aversion	“No local subjects” / “Different epidemiology/program”
6) Regulatory–PV interface (RMP acceptance as part of approval)	Misalignment of RMP/PSMF expectations vs local PV infrastructure; differing safety communication expectations; signal response variability	“RMP measures won’t work locally” / “We need additional local commitments”
7) Labels/PI (core text alignment)	Multiple rounds of country-specific edits, advisory committee divergence, translation/format issues causing delays	“Our label must be unique”
8) Data confidentiality for reliance (assessment/inspection outputs)	No legal pathway to receive confidential assessment/inspection reports; reliance becomes “thin”	“We cannot decide without full report access”

SEARO Regulatory Interdependence Strategy 2026

 CURRENT SYSTEM FRICTION	 24-MONTH IMPLEMENTATION TARGETS	RC
 Acceptance of WHO ePQS Dossier	✓ Abridged Review Checklist operational across pilot NRAs	
 Duplicate GMP Inspections Multiple inspections of same site	✓ Inspection Verification Pilot (1–2 NRAs)	
 Redundant Lot Testing Full re-testing despite stable history	✓ Testing Rationalisation Pilot for PQ-listed vaccines	
 Divergent PAC Classification Same change treated differently across countries	✓ PAC Fast-Lane Framework agreement	
 Unpredictable Timelines Iterative question cycles, no harmonised clocks	✓ Defined Review Timelines for abridged pathway	

ACTION POINT SUMMARY ON REGULATORY WG

DCVMN Expectations	RC DCVMN	RC SEARO	TIMELINE
1. Dossier Harmonization	KG		
- Technical evaluation (cmc, preclinical and clinical) and acceptance	MA and RM		
2. sample testing and acceptance	PD		
3. site inspection and acceptance	KJ		
4. DCVMN Country manufacturers Feedback on NRA (SEARN)	SG		
5. Reliance Procedure implementation	SC		