Regulatory and PV Working Groups Meeting with WHO SEARO

16th Feb 2026- Hotel Andaz, New Delhi, India

Participants from WHO SEARO: Dr. Adrien Inoubli (AI), Dr. Anil Chawla (AC)

Participants from DCVMN: Rajinder Suri (RS), Kumar Gaurav (KG) & Yamini Bhatt (YB)- Panacea Biotec, Manish Mahajan (MM)-Virtual, Subhodeep Chakraborty (SCh) & Devang Patel (DP)-Zydus Life Sciences, Ashna Pema (AP) & Reza Bosman (RB)- Biovac, Bruno Antonio De Oliveira (BO) -Butantan, Chetanraj Bhamare (CB) & Mandar Kshirsagar (MK)-SIIL, Devi Prasad Sahoo (DPS) & Karunakaramaiah Jangam (KJ)- Indian Immunologicals, Sravan Kumar (SrK) & Pradip Das (PD)- Biological E,Rini Mulia (RM) & Viska Indriani (VI)- BioFarma, Katharina Harmann (KH), Malika Almansouri (MA), Sonia Villaseñor (SV), Prerna Kumar (PK).

Welcome and introductions

RS welcomed the group, including representatives from WHO SEARO, DCVMN, Consultants and vaccine manufacturers, followed by a round of introductions.

DCVMN recap of WHO-SEARO meeting in August 2025

SCh gave a summary of the discussions that WHO-SEARO and DCVMN first had in August 2025 highlighting the following topics:

- Regulatory harmonization and reliance are critical priorities
- Promotion of reliance and CRP (Collaborative Registration Procedure) for faster approvals
- Vaccine surveillance & pharmacovigilance need major strengthening to improve data collection and sharing
- Need a common platform for manufacturers and regulatory authorities for AEFI monitoring
- Begin collaborative work with achievable, high-impact initiatives
- Address vaccine hesitancy together
- Build long term SEARO–DCVMN collaboration framework.

Strengthening Vaccination Programs in Southeast Asia

Dr. AI gave a presentation on the role of WHO Regulatory System strengthening program, which has two main objectives:

1) Build capacity in Member States consistent with Good Regulatory Practices through the WHO Global Benchmarking Tool (GBT), and

2) Promote regulatory cooperation, convergence and transparency through networking, work-sharing and reliance.

He also introduced **SEARN** (Southeast Asia Regulatory Network), a voluntary association of NRAs, member-state led (10 NRAs are represented), mainly about information sharing, collaboration and convergence, with six working groups on Quality, especially National Quality

Control Lab, Regulatory Strengthening, Vigilance, Information Sharing, and two specific working groups on Medical Devices and Traditional medical products. SEARN has a capacity building platform with the aim to support the national regulatory authorities in moving towards a competency-based approach to their work.

SEARN has undertaken many initiatives on reliance; if first towards building convergence, defining reliance, and agreeing on what would be the minimum information that is required for reliance, and second identifying key criteria that are required to categorize reference regulatory authority. Their website provides a reliance map.

Dr AI also informed that their WG on vigilance is already working on two pilots. He encouraged the audience to explore the SEARN website as it contains relevant information on regulatory and PV activity relevant not only to SEARO but to all DCVMN members. The SEARN Regulatory WG is involved in the GBT and GRP initiatives in the region.

In the follow-on discussion, he clarified that it is too early to talk about harmonization; the first step is convergence, this will facilitate access of manufacturers to submit dossiers of vaccines to different NRAs in the region. The SEARN Regulatory WG is involved in implementing the WHO GBT to establish Good Regulatory Practices; it is also focused on developing a network of Regional Centers of Excellence to train coordination centers that will run trainings for NRAs on a regular basis. These centers will train on product-specific convergence. There is no consensus yet for mutual recognition. DCVMN emphasized to also have manufacturer participation in SEARN to raise pertinent challenges they face in the region.

Regarding regulatory inspections, WHO has been working very closely with regulators and manufacturers to bridge the gap on how each of them sees the regulation; dossier review is also part of it. WHO is working actively with the NRAs to increase their maturity level to level 3, once reached; this will be public information.

Dr. AC shared a proposal of collaboration between SEARO and DCVMN, which includes:

- Implementing a WHO-hosted Pharmacovigilance dashboard for vaccines based on their safety database (VigiBase); AI based with data integration and analysis. This will also help supply forecasting for 5-10 years, with information of inventories at all levels, and to prevent vaccine shortages.
- All stakeholders such as NRAs, NCLs, Vaccine manufacturers, importing countries and MoH, UN Agencies (UNICEF, GAVI) will have access on a role-based onboarding via registration portal.
- It will have real-time data tracking capability, including production monitoring by manufacturers, lot release, inventory at sites and warehouses, shipment tracking, and delivery status.
- There will be apps for doctors / healthcare providers to register the vaccine used, and vaccine safety data is fed into the app so it can be transmitted directly to the NRA.
- The project will have 4 phases including development and pilot testing, National rollout and training, regional integration and continuous improvement, and potential global expansion with WHO HQ.
- Confidentiality will be carefully protected.

Discussion:
While the initiative was well received amongst the members, challenges were identified, starting with the fact that the manufacturers will be requested to share privileged confidential information which is proprietary market intelligence. Sharing inventories data would be very delicate. Likewise, with Pharmacovigilance, the information should not reach the competitors. The group suggested to provide manufacturers with filtered product-specific data from VigiBase. Another challenge which the manufacturers also highlighted was sharing repeat information on different portals and suggested having access to existing single portal like ePQS to have all data at one place.
These topics discussed above must be taken into consideration and addressed before taking action.

Dr. AC presented the framework of collaboration between SEARO and DCVMN. He emphasized the need of working together to increase access to vaccines and promote life-course immunization (not only for children) as well as ensuring vaccine confidence. This will be a very transparent platform, and the policies will be with WHO. The proposed key areas of collaboration include timely and equitable access, robust AEFI surveillance and PV enhancement, acceleration of new vaccine introductions, regional pooled procurement, research, innovation & evidence generation, tackling vaccine hesitancy, establishing regional Centers of Excellence, emergency preparedness & pandemic response.

For NRAs Regulatory Strengthening DCVMN CEO or delegate can join CIP Network as an observer. DCVMN will check this possibility and submit application to CIP Network secretariat. The proposal included the establishment of a Joint Coordination Committee (JCC) to solve common problems. WHO-SEARO would provide strategic direction and programme design for implementation through WHO or partners, will monitor and evaluate, and will safeguard WHO's neutrality in policy. DCVMN's role would be representing manufacturers & coordinating engagement, mobilizing support, facilitating structured industry dialogues, mapping member priorities & emergency response coordination. WHO will manage conflict of interest with transparency and due diligence declarations. There will be no product or manufacturer endorsement. Technical workshops will be aligned with WHO standards.

Conclusion on DCVMN-WHO Collaboration Strengthening Initiative

The Regulatory WG proposed 5 action points, and PV WG proposed 3 action points. Participants agreed to prioritize small, achievable goals to build trust and collaboration, with a focus on:

1. A multi-stakeholder workshop (WHO, UMC, NRAs, DCVMN, lawyers from the governments of the different countries) to define rules for sharing AEFI data with manufacturers.
2. Convergence workshop: Use a vaccine of regional interest (e.g., Dengue) to test the joint dossier review process.
3. Technical training to NRAs: Reliance Pathways, GMP Inspection readiness, PV compliance, Dossier submissions and PV inspections standalone.
4. Propose SEARN Engagement: DCVMN will write to the SEARN Steering Group to request a formal annual dialogue with NRAs

Next Steps
DCVMN:

- Propose a vaccine for the SEARN Convergence Workshop pilot.
- Draft a letter to the SEARN Steering Group requesting for the opportunity to participate in an annual dialogue.
- Prepare a note on the three agreed-upon action points (Regulatory convergence/PV data sharing/Technical Training)

WHO:

- Share the SEARN Convergence Workshop concept note with DCVMN.
- Organize the multi-stakeholder workshop on PV data sharing.
- Plan the NRA training workshop using real dossiers.

Notes taken by SV
16th Feb '26

Rajinder Suri
CEO- DCVMN International