Regulatory Strategies for Reliance

DCVMN INTERNATIONAL
Developing Countries Vaccine Manufacturers Network International

28th to 30th October 2025

Regulatory Reliance & Collaboration

- **Regulatory Reliance** (RR) is the act whereby the regulatory authority in **one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution**, or to any other authoritative information, in reaching its own decision *
- The **relying authority remains independent, responsible and accountable regarding the decisions taken**, even when it relies on the decisions and information of others *

Patients & HC Providers
Timely access to safe, effective and quality medical products

Manufacturers
Streamlined management of regulatory submissions and global supply systems

NRA's
Efficient utilization of resources by avoiding duplication of work, strengthening the regulatory system, maintaining sovereignty over decision-making

Reliance promotes efficiency (for agency and company), when fully implemented

* ***Good Reliance Practices***, *Annex 10 of the Fifty-fifth report of WHO Expert Committee on Specifications for Pharmaceutical Preparations: (TRS 1033)*

Regulatory Reliance & Collaboration

- **Harmonized Regulatory Pathways**
- **Collaborative Registration Procedure** (CRP) - WHO PQ or SRA
  - *Awareness of vaccine CRP with more no's of local NRAs and vaccine manufacturers (trainings at regional level).*
  - *Success story of CRP for Pharma (medicines) to be replicated for PQ'ed vaccines*
  - *Reliance on the functional (semi-stringent) NRA may expedite review and registration of new vaccines & approval of PAC (Post Approval Changes)*
  - *Lifting the functional NRAs to stringent NRA*
- **Reliance for GMP Inspections** on NRA's designated as ML-3 and PIC/S countries and their Inspection Reports as well as GMP status
- **Recognition of National Control Testing** Laboratories
- Reliance for "**PQ Consistency**" Testing

Proposed Solution for Regulatory Convergence & Reliance

- Common harmonized Initial Registration Dossier as well as the Post-approval Variation package (fit for purpose) across the globe
- Policy and advocacy for Regulatory Convergence on outstanding Country-specific requirements, *e.g., common labelling requirements (similar to the EU countries)*
- Considering the quality risk, the post-approval changes can follow different approaches ranging from implementation of change under company QMS for changes with minor impact to Prior approval:

Types of Post-Approval Changes	Approach as per the Variation's Current Guideline *(V.7.July 2015)*	Proposed Approach based on Regulatory Convergence
Minor Changes (Type N)	**To be notified** within one month after approval by the NRA *(File, wait for 30 days and implement)*	No change
Moderate Changes (Type R)	**Annual reporting** *(Implement and file)*	No change
Major Changes (Type A)	**Prior-approval** *(File, wait for approval and implement)*	**Prior-approval** *(File, wait for 75 days and Implement)*

THANK YOU