Partners Roles and Responsibilities in Ensuring Vaccines Safety

07 FEB 2017

Pharmacovigilance Programme of India (PvPI)	Adverse Event Following Immunization (AEFI) Secretariat	Central Drugs Standard Control Organization (CDSCO)
1. Indian Pharmacopoeia Commission, under the aegis of Ministry of Health and Family Welfare (MoHFW) functions as National Coordination Centre (NCC) for PvPI to monitor, report, collate and analyse adverse events due to medicine and vaccines. 2. PvPI has recognised public & private hospitals as an Adverse Drug Reaction Monitoring Centres (AMCs) across India. 3. The PvPI team at AMC shall be responsible for monitoring of serious & non serious AEFIs in public & private hospitals of their region and reporting to NCC. The AMCs shall also share reported serious AEFI with the District Immunization Officer (DIO) & State EPI Officer (SEPIO) immediately through Serious AEFI Case Notification Form. 4. A serious Individual Case Safety Reports (ICSRs) of AEFI received at NCC shall be immediately communicated to AEFI Secretariat & Pharmacovigilance division of CDSCO for further action at their end. Whereas non serious ICSRs shall be communicated on monthly basis.	1. The National AEFI Secretariat has been set up in Immunization Technical Support Unit (ITSU) through a tripartite agreement with CDSCO, PHFI and Immunization Division, MoHFW to provide technical support to the National AEFI Surveillance Programme which is a part of the Universal Immunization Program (UIP). 2. The National AEFI Secretariat shares with the CDSCO soft copies of reported AEFIs (weekly); linelist of reported deaths and clusters (weekly); linelist of all reported serious AEFIs on a monthly basis (monthly). 3. AEFI Secretariat shall follow up on all serious AEFIs (with AEFI Case Notification Form) reported by AMCs of PvPI with SEPIO/DIO through concerned Zonal consultants for reporting through CRF and investigation (PCIF/FCIF, etc). 4. National AEFI Committee through its Causality Assessment sub-committee conducts regular Causality Assessment (CA) meetings for AEFI cases; summarizes the CA in an anonymized linelist for sharing with MoHFW (for public on website) and further sharing with CDSCO and PvPI as part of the Indian NRA.	1. CDSCO is the National Regulatory Authority which ensures safety, efficacy, and quality standards of pharmaceuticals, medical devices and vaccines in India. 2. The Pharmacovigilance division of CDSCO (HQ) functions in close coordination with the PvPI; Immunization Division; AEFI cells for the continuing monitoring of vaccine safety. 3. Regulatory actions are initiated by CDSCO in case the qualities of implicated vaccines are indicated to be responsible for the adverse event in the causality assessment report. 4. Drug Inspector deputed by the state drug controller department and the concerned CDSCO (zonal) officer under whose jurisdiction the AEFI occurred, take part in joint investigation along with DIO. 5. CDSCO is responsible for taking appropriate regulatory decisions and actions on the basis of recommendation of PvPI and AEFI secretariat.

5. NCC-PvPI invites experts from AEFI Secretariat for signal review meetings along with CDSCO. The observations of Signal Review Panel (SRP) related to AEFIs shall also be submitted to National AEFI committee for further examination and recommendations. 6. India specific signals identified are recommended to CDSCO for appropriate regulatory actions.	5. AEFI Secretariat shall inform the CDSCO of formation of any central team for conducting special investigations in the states so that joint investigations can be conducted.	
Signed on behalf of IPC, NCC-PvPI **(Dr. G.N. Singh)** Secretary-cum-Scientific Director, Indian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India, MoHFW, GoI, Ghaziabad **Date:** 07 FEB 2017	**Signed on behalf of AEFI Secretariat** **(Dr. M.K. Aggarwal)** Deputy Commissioner, Universal Immunization Programme Immunization Division MoHFW, GoI, Nirman Bhawan, New Delhi **Date:** 07 FEB 2017	**Signed on behalf of CDSCO** **(Dr. G.N. Singh)** Drugs Controller General (India) Central Drug Standard Control organization Directorate General of Health Services MoHFW, GoI, FDA Bhawan, New Delhi 07 FEB 2017 **Date:**