Partners Roles and Responsibilities in Ensuring Vaccines Safety

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 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 AMC centres shall also share reported serious AEFI with the District Immunization Officer (DIO) & State EPI Officer (SEPIO) immediately in their respective centres. 4. A serious Individual case safety reports (ICSRs) due to vaccines received at NCC shall be immediately communicated to AEFI Secretariat & AEFI 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 the reported AEFIs with the CDSCO on a weekly basis through the soft copy as well as print copy. 3. AEFI Secretariat shall receive all serious and non-serious reports from NCC-PvPI and forward the information to concerned Zonal consultant for further follow up at the state and district level by the SEPIO/DIO to ensure 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 AEFI 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 incited 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.

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5. NCC-PvPI invites experts from AEFI Secretariat for signal review meetings. 6. India specific signals identified are recommended to CDSCO for appropriate regulatory actions.	5. Responsible to coordinate with respective AMC for further follow up/investigation in case of serious AEFI	
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:** 25 NOV 2016	**Signed on behalf of AEFI Secretariat** **(Dr. M.K. Aggarwal)** Deputy Commissioner, Universal Immunization Programme Immunization Division MoHFW, GoI, Nirman Bhawan, New Delhi **Date:** 25 NOV 2016	**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 **Date:** 25 NOV 2016