



STANDARD OPERATING PROCEDURE

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SOP No.

IPC/PvPI/NHP/001

Division

NHP-AEFI Division

Revision No.

02

Effective Date

02/01/2017

Review Date

01/01/2020

Title: Processing and Communication of AEFI-ICSRs

1.0 OBJECTIVE

To lay down a procedure for monitoring, reporting and communication of AEFI-ICSRs in Pharmacovigilance Programme of India.

2.0 SCOPE

This Standard Operating Procedure shall be applicable to Pharmacovigilance Programme of India.

3.0 RESPONSIBILITY

- 3.1 The personnel engaged in the PvPI activity shall be responsible for adhering to this SOP.
- 3.2 All the Officers and Section-Incharge shall ensure that this parent SOP has been reflected in the section.
- 3.3 Quality-Manager/Technical-Manager shall ensure overall implementation of this SOP.

4.0 ACCOUNTABILITY

Officer Incharge-Pharmacovigilance Programme of India

5.0 PROCEDURE

- 5.1 NCC-PvPI shall engage in assisting Universal Immunization Programme (UIP) in monitoring the safety of vaccines.

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Reviewed by	<i>Dr. Anand Thota</i>	SA	<i>[Signature]</i>	21/12/2016
Approved by	<i>Dr. V. Kaleshvaran</i>	PSO	<i>[Signature]</i>	22/12/16

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National Coordination Centre-Pharmacovigilance Programme of India

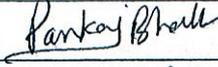
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- 5.2 Immunization Technical Support Unit (ITSU) under UIP, Ministry of Health and Family Welfare, Government of India (MoHFW/ GOI) is the collaborative unit for monitoring AEFI. It coordinates with CDSCO in monitoring of vaccine safety.
- 5.3 A *Serious AEFI Case Notification Form*- shall be filled with suspected ADR reporting form for reporting of Serious AEFI case which shall be notified to the DIO of the district where the vaccine was administered. This duly filled form be scanned and emailed simultaneously to DIO, SEPIO, PvPI and AEFI Secretariat.
- 5.4 AMCs shall be responsible for monitoring and reporting all Serious AEFI-ICSRs immediately to the DIO, SEPIO, AEFI Secretariat and NCC-PvPI. Non-serious AEFI-ICSRs shall be reported on a monthly basis to the NCC-PvPI.
- 5.5 NCC-PvPI shall be responsible for communicating both serious and non serious AEFI-ICSRs to ITSU and AEFI division of CDSCO and a copy to UIP.
- 5.6 Causality assessment of AEFI-ICSRs is entirely different method as compared to drugs; the rational approach is to communicate AEFI-ICSRs further to National AEFI committee for causality assessment.
- 5.7 In case, follow-up is required, NCC-PvPI (AEFI division) / UIP-ITSU/ CDSCO (AEFI division) shall approach AMCs.
- 5.8 For effective communication, roles and responsibilities of stakeholders for vaccines safety has been designed as follows-

5.8.1 Roles and responsibilities of PvPI

5.8.1.1 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, collates and analyse adverse events due to medicines and vaccines.

5.8.1.2 PvPI has recognised public & private hospitals as an adverse drug reaction monitoring centres (AMCs) across India.

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5.8.1.3 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.

5.8.1.4 A serious Individual Case Safety Reports (ICSRs) due to vaccine received at NCC shall be immediately communicated to AEFI Secretariat & AEFI division of CDSCO for further action at their end. Whereas non serious ICSR shall be communicated on monthly basis.

5.8.1.5 NCC-PvPI invites experts from AEFI Secretariat for signal review meetings.

5.8.1.6 India specific signals identified are recommended to CDSCO for appropriate regulatory actions.

5.8.2 Roles and Responsibilities of AEFI

5.8.2.1 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).

5.8.2.2 The National AEFI Secretariat shares the reported AEFIs with the CDSCO on a weekly basis through the soft copy as well as print copy.

5.8.2.3 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.

5.8.2.4 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.

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5.8.2.5 Responsible to coordinate with respective AMCs for further follow up/investigation in case of serious AEFI.

5.8.3 Roles and Responsibilities of CDSCO

5.8.3.1 CDSCO is the National Regulatory Authority which ensures safety, efficacy, and quality standards of pharmaceuticals, medical devices and vaccines in India.

5.8.3.2 The AEFI division of CDSCO (HQ) functions in close coordination with the PvPI; Immunization Division; AEFI cells for the continuing monitoring of vaccine safety.

5.8.3.3 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.

5.8.3.4 Drug Inspector deputed by the state drug controller and the concerned CDSCO zonal officer under whose jurisdiction the AEFI occurred, take part in joint investigation along with DIO.

5.8.3.5 CDSCO is responsible for taking appropriate regulatory decisions and actions on the basis of recommendation of PvPI and AEFI secretariat.

6.0 SAFETY AND PRECAUTIONS

6.1 Do not use any SOP if it is not signed and issued by QA Personnel or the authorized signatories.

6.2 Do not use adhesive tape or whitener on SOP.

6.3 Do not share the SOP information outside the organization.

7.0 REFERENCES: In house

8.0 ABBREVIATIONS

	Name	Designation	Signature	Date
Prepared by	PANKAJ BHATT	Sr. PvA	Pankaj Bhatt	20/12/2016
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Sign. by Dr. P. S. Datta Dt. 22/12/2016

Dt. 22/12/2016

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AEFI	:	Adverse Event Following Immunisation
AMCs	:	Adverse Drug Reaction Monitoring Centres
CA	:	Causality Assessment
CDSCO (HQ)	:	Central Drugs Standard Control Organization (Head Quarter)
CRF	:	Case Reporting Format
DIO	:	District Immunization Officer
FCIF	:	Final Case Investigation Format
ICSRs	:	Individual Case Safety Reports
ITSU	:	Immunization Technical Support Unit
MoHFW/ GOI	:	Ministry of Health and Family Welfare / Government of India
NCC	:	National Coordination Centre
NRA	:	National Regulatory Authority
PCIF	:	Preliminary Case Investigation Format
PHFI	:	Public Health Foundation of India
PvPI	:	Pharmacovigilance Programme of India
QA	:	Quality Assurance
SEPIO	:	State Expanded Programme Immunization Officer
SOP	:	Standard Operating Procedure
UIP	:	Universal Immunisation Programme

9.0 ANNEXURE(s):

Annexure I : Log book record for communication of Serious AEFI-ICSRs to CDSCO, ITSU & UIP. (Format No. IPC/PvPI/NHP/001-F01)

	Name	Designation	Signature	Date
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