

**INDIAN PHARMACOPOEIA COMMISSION
NATIONAL COORDINATION CENTRE
PHARMACOVIGILANCE PROGRAMME OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
SECTOR -23, RAJ NAGAR, GHAZIABAD – 201002**

SIGNAL REVIEW PANEL UNDER PvPI

The WHO has defined a signal as:

“Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously” An additional note says: “Usually more than one report is required to generate a signal, depending on the seriousness of the event and the quality of the information”.

A signal is therefore a hypothesis together with data and arguments. A signal is not only uncertain but also preliminary in nature: the situation may change substantially overtime one way or another. A signal may also be supported by more documentation which further qualifies a simple association of a drug product with an ADR, for examples, information on the range of severity of a reaction, its outcome: postulating a mechanism; indicating an “at risk” group; a dose range which might be more suspected; or suggesting a pharmaceutical group effect or indeed a lack of such an effect by a particular drug.

SIGNAL is produced by the National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI)-Indian Pharmacopoeia Commission (IPC) and presents information derived from the NCC-PvPI national ICSR database management system i.e. VigiFlow. This database contains summary of case reports of suspected adverse drug reactions, submitted by Adverse drug reaction Monitoring Centres (AMCs) across the India.

PvPI Signal Review Panel consists of national, experienced medical professors, regulatory authority members usually affiliated to a governmental or academic institution invited by NCC-IPC. Under the responsibility of PvPI they assess- the database for the occurrence of signals of possible importance for public health, drug regulation, and science.

The identified SIGNALs are thus varying levels of suspicions derived from examination of data in the PvPI-VigiFlow database. As emphasized above, SIGNAL contains different hypotheses, primarily intended to inform national regulatory authorities, which may in turn consider the needs for possible further action (for instance further evaluation of source data, or a study for the testing of a hypothesis). The dissemination of identified SIGNALs by the PvPI is currently restricted to AMCs, regulatory authority staff and their advisers participating in the Pharmacovigilance Programme of India. The NCC takes no responsibility for contacting all marketing authorization holders.

Central Drugs Standard Control Organisation and Indian Pharmacopoeia Commission are responsible for deciding further action including communicating the information in SIGNAL to relevant health professionals, and to the responsible market authorization holders, with in their jurisdictions.

In order to continue a healthy debate, we encourage all recipients of SIGNAL to comment briefly (about 1000 words) on individual topics. The comments will be published in the upcoming PvPI-News Letters.

The Signal review panel under PvPI has been constituted by Ministry of Health & Family Welfare, Government of India with a team of 18 members which consists of One Chairperson, One Member Secretary and Sixteen members.

Terms of References

1. Collation and analysis of information from the ICSRs submitted to NCC-PvPI through VigiFlow by the ADRs monitoring centres enrolled under PvPI.
2. Define bio-statistical methods to be followed for analysis.
3. To create standardized post analytical reports that will help in understanding the information that is derived from ADRs
4. To decide on actionable indicators.

Sl No	Name	Designation	Role in Panel
1	Dr. Urmila Thatte	Professor & Head, Dept of Clinical Pharmacology, Seth GS Medical College &KEM Hospital, Mumbai	Chairperson
2	Dr. Nitin Karnik	Professor of Medicine & In Charge Medicine Intensive Care Unit, Seth Gs Medical College & KEM Hospital,	Member

		Mumbai	
3	Dr. Surinder Singh,	Director I/c, National Institute of Biologicals, Noida	Member
4	Dr. Bikash Medhi	Additional Professor, Dept of Pharmacology, PGIMER, Chandigarh	Member
5	Dr. Rakesh Kochhar	Professor in Gastroenterology, PGIMER, Chandigarh	Member
6	Dr. Praveen Aggarwal	Dept of Emergency Medicine, AIIMS, New Delhi	Member
7	Dr. Suparna Chatterjee	Professor, Dept of Pharmacology, IPGIMER, Kolkata	Member
8	Dr. Aneja	HOD, Pediatrics, Kalawati Saran Hospital & LHMC, New Delhi	Member
9	Dr. B. Aruna Kumari, M.D.(Gynecology)	Modern Govt Maternity Hospital, Hyderabad	Member
10	Prof. Parthasarathy	Dept of Clinical Pharmacy, JSS Medical College, Mysore	Member
11	Dr. M. Vivekanandan	Dept of Medicine, Indira Gandhi Medical College & Research Institute, Puducherry	Member
12	Dr Madhur Gupta	Technical Officer, WHO-India(Country Office)	Member
13	Prof. S Dwivedi	Hamdard Institute Of Medical Sciences & Research, Jamia	Member
14	Dr. Jitendra Kumar Sharma	Senior Consultant & Division Head, Healthcare Financing, National Health System Resource Centre, MoH&FW, Govt of India	Member
15	Dr N K Arora	INCLEM Trust International, New Delhi	Member
16	Dr. B. Adhisivam	Asst Professor, Dept of Pediatrics, JIPMER, Puducherry	Member
17	Dr. Sreejith Parameswaran	Asst Professor , Dept of Nephrology, JIPMER, Puducherry	Member
18	Dr. V. Kalaiselvan	Principal Scientific Officer, IPC, Ghaziabad	Member Secretary