



Newsletter

PHARMACOVIGILANCE PROGRAMME OF INDIA (PvPI)

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STRIVING FOR EXCELLENCE: A PROFESSIONAL 'SKILL DEVELOPMENT PROGRAMME' FOR HEALTHCARE STAKEHOLDERS

Secretary-cum-Scientific Director's Message



Dear Readers,

It gives me immense pleasure to delve on developments during the Jan-Mar 2017 quarter that could mark a turning point for drug-use and safety-monitoring among Indian masses.

At the outset, I wish to congratulate Pharmacovigilance Programme of India (PvPI) under the aegis of Indian Pharmacopoeia Commission (IPC), Ministry of Health & Family Welfare (MoHFW), for successful assessment by World Health Organization-National Regulatory Authority (WHO-NRA) Global Benchmarking Tool (GBT). PvPI is rapidly gaining momentum in India and has been awarded a coveted maturity level of 4 out of 5.

Another landmark achievement in light of Pradhan Mantri Kaushal Vikas Yojana (PMKVY) is the commencement of Skill Development Programme on 'Basics and Regulatory Aspects of Pharmacovigilance', aimed at enhancing skills of the workforce engaged in the pharmaceutical industry and to effectively meet quality standards. I am happy to note that the first batch of these young Pharmacovigilance professionals has successfully qualified, and is geared for a great journey ahead.

It is noteworthy to mention that PvPI has taken a call to act on antimicrobial resistance (AMR) in the country. PvPI acts by all possible means of interventions like executive orders, educational approach and training aimed at curbing the menace of AMR. To combat AMR, we must strengthen Pharmacovigilance activities at national, regional and district levels to safeguard public health. It is the need of the hour to educate healthcare professionals on rational use of antimicrobials in the country.

I congratulate the entire PvPI team for its relentless efforts aimed at attaining a sustainable system of healthcare for one and all in the country.

Dr G N SINGH

Secretary-cum-Scientific Director,
Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare,
Government of India.



MvPI partners during an induction-cum-training programme for coordinators and research associates, at NCC-PvPI, IPC

During the steering committee's second meeting at IPC, Ghaziabad, on March 21, 2017, Dr G N Singh urged the NCC-PvPI, IPC, to shoulder all MvPI responsibilities with a view to ensuring its smooth functioning.

Dr Singh in his capacity as Secretary-cum-Scientific Director, IPC, has recently issued a circular to 210 Adverse Drug Reactions Monitoring Centres (AMCs) under PvPI, highlighting the following:

- Urgent need for reporting all adverse events due to use of medical devices
- Reporting of adverse events due to medical devices through the specifically-prescribed Medical Device

Adverse Event (MDAE) reporting-form

- Need for close coordination by PvPI with cardiology, orthopaedics and dentistry departments of all AMCs to ensure urgent reporting
- PvPI to develop working relations with biomedical engineers, technical partners and healthcare professionals

NCC-PvPI has received as many as 50 Medical Device Adverse Event (MDAE) reports, which included 39 reports due to invasive devices, five reports due to non-invasive devices and six reports related to quality of the medical device.

Induction-cum-training Programme for Newly-recognized AMC Coordinators

CIndian Pharmacopoeia Commission, National Coordination Centre-Pharmacovigilance Programme of India (NCC-PvPI) organised a two-day “Induction-cum-training Programme on Pharmacovigilance” for the coordinators of newly-recognised Adverse Drug reaction monitoring centres (AMCs) under PvPI on February 22-23, 2017 at Indian Pharmacopoeia

Commission, Ghaziabad.

This training delved upon the Basics & Concepts of Pharmacovigilance, Good Pharmacovigilance Practices (GVP), Quality Management System (QMS) of PvPI and Regulatory Aspects of PvPI, including practical sessions and hands-on training on VigiFlow.®

S. No.	STATE	CENTRE NAME	PARTICIPANT NAME
1	Karnataka	Mysore Medical College and Research Institute, Irwin Road, Mysore, Karnataka	Dr Basavanna P L
2	Kerala	Aster Medcity, Cheranelloor, Kochi, Kerala	Dr Ameer Shajahan
3	Telangana	Malla Reddy Institute of Medical Sciences, Quthabullapur, Jeedmetla, Hyderabad, Telangana	Dr M Jamuna Rani
4	Uttar Pradesh	Mata Anandamayee Hospital, Pandit Madan Mohan Malviya Road, Shivala, Varanasi, Uttar Pradesh	Dr Amit Kumar Gupta
5	Bihar	Narayan Medical College & Hospital, Jamuhar, Sasaram, Bihar	Dr Rahul Mohan

TECHNICAL OUTCOME

This induction-cum-training programme provided the coordinators of AMCs an opportunity to learn Good Pharmacovigilance Practices and Quality Management System of PvPI with a view to implementing the same at their centres for ensuring patient-safety.

Advance-Level Pv Training at B J Medical College, Ahmedabad

BJ Medical College, Ahmedabad, which is enrolled as a Regional Training Centre, held a day-long training on Pharmacovigilance on January 20, 2017. This training was organized with the objectives of updating the participants on principles of drug safety, risk assessment and quality management system of PvPI. As many as 96 participants, including AMC coordinators (10), Patient Safety-Pharmacovigilance Associates (08), Medical Faculty (38) and post-graduate students (40), participated in the event. The training was well organized and the participants' knowledge was gauged by pre and post-assessment which assured the

usefulness of training. B J Medical College, Ahmedabad, is committed to organizing such events and continuing to fulfil PvPI's objectives of patient safety.



Inaugural ceremony of training programme at B J Medical College, Ahmedabad, on January 20, 2017