National Accreditation Board for Hospitals & Healthcare Providers
(Constituent Board of Quality Council of India)

NABH/IPC/PvPI/2021/2508 April 15, 2021

Dear Colleague,

This is to inform you that Indian Pharmacopoeia Commission (IPC), an autonomous institution of Ministry of Health and Family Welfare, Government of India has been entrusted with the responsibility related to Pharmacovigilance Programme of India (PvPI) since April 2011. The objective of PvPI is to improve patient safety and welfare of Indian population by monitoring drug safety and thereby reducing the risks associated with the use of medicines. Pharmacovigilance is based on sound scientific principles and is an integral part of effective clinical practices. This discipline needs to develop further to meet the demands of public health for which continuous monitoring of drugs is essential. Such monitoring will help in assessing, monitoring and detecting adverse effects of drugs, their interactions, taking corrective intervention, selection of safer drugs for rational prescribing etc.

The Adverse Drug Reaction (ADR) reporting culture among healthcare professionals needs to be scaled up by enrolling all the NABH accredited Hospitals as ADR Monitoring Centre (AMC) under PvPI. Therefore, in order to ensure further strengthening of Pharmacovigilance Programme of India, I would request all NABH accredited Hospitals/organizations to get enrolled under PvPI as ADR monitoring Centre (AMC). Your support and participation will help increase data collection, analysis and achieving full potential of drug of drug therapy.

You can download the Letter of Intent available on the website of Indian Pharmacopoeia Commission (www.ipc.gov.in) as well as on the website of NABH.

The duly fill in Letter of Intent for enrolment as AMC under PvPIshould be sent to:

The Secretary-cum-Scientific Director
Indian Pharmacopoeia Commission
Sector 23, Raj Nagar
Ghaziabad – 201002

It is emphasized that reporting of adverse events shall not have any legal obligation on reporter; therefore your active participation in ADR reporting is need of the hour for the sake of patient safety and optimal clinical outcome.

Warm regards,

(Dr. Atul Mohan Kochhar)
CEO-NABH

Brief Information:

Pharmacovigilance Programme of India (PvPI) and Advantages of Enrolment as Adverse Drug Reaction Monitoring Centre (AMC) under PvPI

Adverse drug reaction (ADR) is one of the leading causes of morbidity and mortality worldwide. The consequences of ADRs burden the healthcare system with increased cost of therapy and prolongation of hospitalization. India is a vast socio-ethnic, biodiverse country with different healthcare facilities. Due to its varied geographical expanse, disease patterns and different practising systems of medicine, Indian population encounters Adverse Drug Reactions which could be entirely different from other countries. It is, therefore, imperative to evaluate the safety of medicines in a scientific manner through a highly specialized system i.e. Pharmacovigilance.

So, in order to gain a complete safety profile of medicine in real world scenario, continuous post-marketing surveillance system is required that can be accomplished through Pharmacovigilance System. Any known or unknown adverse events can be monitored through this system. Understanding the compelling need for a stable ADR reporting system in India, Ministry of Health and Family Welfare, Government of India launched a robust techno-science-based system in the form of Pharmacovigilance Programme of India (PvPI) in July 2010, initially housed at All India Institute of Medical Sciences (AIIMS), New Delhi as the National Coordination Centre (NCC). Further, in order to safeguard the health of Indian Population and take PvPI to greater heights and implement this programme in a more effective way, the Ministry of Health and Family Welfare, Government of India recasted this programme and shifted the National Coordination Centre at Indian Pharmacopoeia Commission (IPC), Ghaziabad vide an Order dated 15th April, 2011.

The mission, vision and Objectives of PvPI are as under:

Mission

To safeguard the health of Indian population by ensuring that the benefits of use of medicine outweigh the risks associated with its use.

Vision

To improve patient safety and welfare of Indian population by monitoring safety of medicines, thereby reducing the risk associated with their use.

Objectives

The objectives of the PvPI are to:

- Create a nation-wide system for patient-safety by ensuring drug-safety
- Identify and analyse new signals from the reported cases
- Analyse the benefit-risk ratio of marketed medications
- Generate evidence-based information on safety of medicines
- Support regulatory agencies in the decision-making process on use of medications
- Communicate safety information on use of medicines to various stakeholders for preventing/minimizing the risk
- Collaborate with other national Centres for exchange of information and data management
- Provide training and consultancy support to other National Pharmacovigilance Centres across the globe
- Promote rational use of medicines
- Emerge as a National Centre of Excellence for Pharmacovigilance Activities

Pharmacovigilance Programme of India (PvPI) is Government of India's flagship drug safety monitoring programme which continuously monitors adverse drug reactions from the use of medical products across the country. Realizing the importance of Pharmacovigilance in recent years and the need for evidence based indigenous data for policy decisions, the PvPI has succeeded in establishing a nationwide network of 346 ADR monitoring Centres (AMCs) across the country. PvPI has been initiating an intensive and concerted effort to gather scientific information on Adverse Drug-Reaction monitoring from hospitals to evaluate the benefit and risks of medicines. The gathered Adverse Event/Adverse Experience data are collected, collated and analyzed for ADRs at NCC-PvPI, IPC serves as a major source of evidence-based scientific support which is provided to the National Regulatory Authority, the Central Drug Standards Control Organization (CDSCO) for regulatory interventions. It is of worthy interest to note that NCC-PvPI has identified and issued 118 drug safety alerts, 57 Prescribing Information Leaflet (PIL) changes including 7 signals for sensitization of stakeholders. NCC is continuously communicating the findings of PvPI to Central Drugs Standards Control Organisation for regulatory actions.

India-specific Individual Case Safety Reports (ICSRs) reported under the umbrella of PvPI is to a tune of about 5 lacs and currently India stands tall in becoming 9th largest contributor of ADR data to WHO database. Moreover, the quality of ICSRs from India is much higher as compared to rest of the world.

Recognising the strength and progressive journey of PvPI in the area of Pharmacovigilance, it is a matter of great honor and pride for the nation that NCC-PvPI has been recognized as the "WHO Collaboration Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services". PvPI has also been working in close collaboration with other National Health Programmes being run in the country such as National Tuberculosis Elimination Programme (NTEP), National AIDS Control Organization (NACO) and National Vector-Borne Disease Control Programme (NVBDCP), Universal Immunisation Programme (UIP) etc.

Several tools and methods have been introduced by the PvPI including Suspected ADR Reporting form (For Healthcare Professionals), Medicines Side Effect Reporting form (For consumers) in Hindi, English and other vernacular languages, Mobile App (ADR PvPI), PvPI Helpline (Toll-free 1800 180 3024), etc. For further details visit www.ipc.gov.in. NCC-PvPI organizes regular training programmes including skill development programmes on Pharmacovigilance to enhance knowledge, skills and practice of stakeholder's and to promote quality and safety of medicines manufactured and marketed in India.

Therefore, effective implementation of Pharmacovigilance in healthcare facilities will provide a dynamic and stable system to monitor the ADR reporting mechanism about safety of the drugs used in the country. This will reduce our dependence on western world data for taking regulatory decisions on drug safety on account of evolution of evidence based drug safety mechanism. Therefore, the Pharmacovigilance actions and ADR monitoring centres need to be scaled up and is the need of the hour.

Advantages of Enrolment as an AMC

The Advantages of Enrolment as an AMC are:

1. Health partner for the Nation-wide ADR Reporting System
2. Access to WHO Global safety database, VigiFlow to evaluate benefit-risk assessment of Medicines
3. Eligible for Financial/Manpower assistance and other expenses for training/ conferences/telephone/internet etc.
4. Scientific Publications/ Case Studies/Project related to pharmacovigilance
5. Reduce India's dependence on western world data for taking regulatory decisions on drug safety.
6. Boost Public confidence in safety of medicines

For further details, please contact at : pvpi.ipc@gov.in**;** www.ipc.gov.in