INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre - Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India

"How to develop a positive culture of Adverse Event Reporting *by* Pharmaceutical Industries/Marketing Authorization Holders?"

April 29, 2021

WEBINAR

WHO SHOULD ATTEND?

Professionals working in Pharmacovigilance, Quality Assurance & Regulatory Affairs in Pharmaceutical Industries

REGISTRATION DETAILS

- Registration Fee : Rs. 1000/- (*Including 18% GST*) *per participant*
- Please fill in & submit online Registration Form available on www.ipc.gov.in & www.cdsco.gov.in

ORGANIZED BY

Indian Pharmacopoeia Commission
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Last Date of Registration
April 27, 2021

"Let us join hands with PvPI to ensure Patient Safety"

INFORMATION BROCHURE

Objective

To sensitize Drugs Manufacturers, Importers, Distributors and other stakeholders for the effective implementation/strengthening of pharmacovigilance system in pharmaceutical industries/Marketing Authorization Holders (MAHs) site.

Background

Pharmacovigilance (PV) has purpose to improve patient care and safety in relation to the use of medicines and also plays a major role in clinical practice and the development of public health policy. It also contributes to the assessment of benefit, harm, effectiveness and risk of medicines, to the prevention of harm, and maximization of benefit to the patient. The Ministry of Health & Family Welfare (MoHFW), Government of India, therefore launched a Nationwide Pharmacovigilance Programme of India (PvPI) in Year 2010 to monitor Adverse Drug Reactions ensuring the benefits of drugs outweigh the risks associated with its use. Indian Pharmacopoeia Commission (IPC), autonomous body under the MoHFW has been functioning as National Coordination Centre (NCC) for PvPI since April 15, 2011. To monitor ADRs, Adverse Drug Reactions Monitoring Centres (AMCs) have been established under PvPI across the country.

As per the **Schedule M of Drugs & Cosmetic Rules 1945** there under, **section 28.2** mentioned as "reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to the concerned Licensing Authority". Furthermore, the **New Drugs & Clinical Trial Rules, 2019** mandates for the requirement of the Pharmacovigilance system to be put in place for post marketing assessment of new drugs. In this regard, NCC-PvPI, IPC, a WHO-Collaborating Centre for Pharmacovigilance in public health programme & regulatory services, in collaboration with CDSCO has developed "Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products", which was released by the then Secretary, MoHFW, Govt. of India on September 29, 2017 and has been effective from January 1, 2018.

About the Workshop

The said workshop is organised by IPC, NCC-PvPI aimed to;

- ✓ Discuss the setup/strengthening of Pharmacovigilance system at Pharmaceutical Industries/MAHs site.
- ✓ Current issues and challenges for reporting of ADRs by Pharmaceutical Industries/MAHs to IPC, NCC-PvPI.

Expected Outcome

- ✓ The whole exercise would help the MAHs to establish & strengthen the PV system which would enable them to report ADRs/AEs to NCC-PvPI, IPC.
- ✓ In the process MAHs' queries & doubts would also be addressed to make PV system stringent.

Contact Persons

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