INDIAN PHARMACOPOEIA COMMISSION

National Coordination Centre - Pharmacovigilance Programme of India

Ministry of Health & Family Welfare, Govt. of India

14th

Regional Workshop via Webinar on "Pharmacovigilance & Esablishment of Pharmacovigilance System in Pharmaceutical Industries - A Way Forward On October 9, 2020

Who should attend?

Professionals working in Pharmacovigilance, Quality Assurance and 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

October 7, 2020

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

Objective

To sensitize Drugs Manufacturers, Importers, Distributors and other stakeholders to develop/ strengthen Pharmacovigilance system as per the Good Pharmacovigilance Practices (GVP).

Background

Pharmacovigilance has purpose to improve patient care and safety in relation to the use of medicines and also play a major role in clinical practice and the development of public health policy. 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 outweighs the risks associated with its use. Indian Pharmacopoeia Commission (IPC), autonomous institutes 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 Y of Drugs & Cosmetic Rules 1945 and the Gazette notification GSR 287 (E) dated March 8, 2016 the setting up of Pharmacovigilance system is mandatory for all MAHs. 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, National Coordination Centre – Pharmacovigilance Programme of India, Indian Pharmacopoeia Commission, a WHO-Collaborative Centre for Pharmacovigilance in collaboration with CDSCO has developed "Pharmacovigilance Guidance Document for MAHs of Pharmaceutical Products", which was released by the then Secretary, Health, 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/strengthen of Pharmacovigilance system at MAHs site.
- ✓ Current issues and challenges for reporting of ADRs by 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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