

## **Report of Workshop on AYUSH Pharmacovigilance**

A national level workshop on Pharmacovigilance was organized by Intermediate Pharmacovigilance Centre, NIA Jaipur on 17<sup>th</sup> & 18<sup>th</sup> March 2024.

All JRFs & Coordinators who report to Intermediate Pharmacovigilance Centre, NIA Jaipur were invited to attend this workshop. Dr Apoorva Sangoram Coordinator & Dr. Vaibhavi Sabne JRF were present from PPvC Tilak Ayurved Mahavidyalay Pune.

Main Objectives of this workshop were-

1. Uniformity in work establishment at all PPvC Centres
2. Building rapport with the team & focus on interaction regarding exchange of knowledge & difficulties faced by PPvC

First day of workshop began with the Inaugural ceremony. Prof. M.C. Sharma Sir, Ex-Director, NIA, Jaipur was the chief guest for the ceremony. Also stalwarts like

Dr. Galib, Head of National Pharmacovigilance Centre, New Delhi,

Prof. Vandana Roy, HOD, Pharmacology

Dr Amar Singh Kaviya, Drug Controller Rajasthan, graced the Dias.

After lighting the holy lamp & Lord Dhanvantari poojan, introductory speeches were delivered by the guests. Importance of Pharmacovigilance in today's era, accepting the facts about the chikitsa & reporting of ADRs & its necessity was highlighted by all the speakers.

The scientific sessions began right after Inauguration ceremony. Prof Vandana Roy began with her lecture on 'Monitoring Drug Safety: Looking beyond spontaneous reporting systems' Objective of the lecture was,

1. To ensure drug safety for the patients
2. Various ways of Data mining & drawing scientific conclusions according to data presented

Ma'am highlighted Drug safety monitoring during Pre-marketing clinical trials as well as Post-marketing surveillance. Advantages & Limitations at these stages were discussed in depth. Importance of EHR (Electronic Health Records), Usage of IT softwares were also explained in detail. Many new ideas, different ways of Data mining, Usage of Social media for our advantage etc. such new horizons were introduced by the speaker.

Next session was held by Dr. Mohammad Khalid Sir, Asst. Drug controller cum Licensing Authority, Unani. His topic was Regulatory Canvas of AYUSH Pharmacovigilance. What is the mandate for PPvC Centres regarding reporting of Misleading Advertisements? Aims & Objectives of DMR(OA) Act? What comes under D7C Act? Specifically DMR(OA) Act, 1954, its importance, need & specific sections such as Section 3,4,5 were discussed in detail. Specific terminologies, their meanings according to Law was highlighted. Importance of understanding the Act before reporting was emphasized.

Last scientific session for the day was undertaken by Dr. Galib, Head of NPvC, AIIA, New Delhi. At first Dr. Galib congratulated all the JRFs & Co-ordinators for all the work they are doing as its notice has been taken by Ministry of AYUSH. Dr. Galib said though 105 PPvC Centres are helmed by NPvC, all the ground work is being done by PPvCs, which is creditable. Short comings were also discussed. How to overcome such difficulties were discussed in detail. Many solutions were suggested by Dr. Galib to improve the work which is going on such as,

1. Collaborating with other medical colleges for arranging Awareness programs
2. Exchange of newer ideas with JRFs
3. Introduction of Pharmacovigilance in the clinical trials held at the respective institutes by MD scholars.

On Day 2, Dr. Sudip Rath, HOD Dravyaguna, NIA Jaipur gave lecture on 'Rigorous Pharmacovigilance practices in Ayurveda' Basic principles of Ayurveda, Presence of Pharmacovigilance in various Ayurvedic texts, their correlation was elaborately discussed. He highlighted total ADRs reported since 2018 were 1749. 904 were ADRs related to Ayurveda stream. Out of which only 1 classical drug was reported. According to these reports a conclusion can be drawn out that Drug designing process for Propriety medicines needs to be done deeply. Pre-rationalisation at the time of application is must, Elimination of chance bias is necessary.

Suggestions from all JRFs & Coordinators were welcomed. Dr. Apoorva Sangoram, Coordinator PPvC Tilak Ayurved Mahavidyalay Pune ensured to take initiative in Preparation of the Monogram on Pharmacovigilance in Ayurveda along with interested JRFs.

The workshop concluded with Valedictory Ceremony. Many Stalwarts like Prof. Dr. Meeta Kotecha Maam, Prof. A. Rama Murthy, Prof. Dr. Vandana Roy graced the occasion.