ISCR’s 4th national symposium focuses on enhancing pharmacovigilance excellence in India

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Hyderabad: The Pharmacovigilance Council (PV Council) of the Indian Society for Clinical Research (ISCR) conducted its 4th national symposium on “Enhancing Pharmacovigilance Excellence in India: An Integrated Approach” recently at Hyderabad.

In his opening remarks, Dr Chirag Trivedi, President of ISCR and Chief Guest on the occasion, mentioned: “Pharmacovigilance as a domain has come a long way and is an irrefutable determinant of the life cycle of a drug in clinical development as well as in the post-marketing phases.”

Dr P Usha Rani, Professor and Head, Dept. of Clinical Pharmacology and Therapeutics, Nizam’s Institute of Medical Sciences and also in-charge, Regional Resource Centre for Andhra Pradesh and Telangana under the Pharmacovigilance Programme of India (PvPI) Hyderabad was the Guest of Honour. She added her perspectives on the integrated approach needed for PV in India and urged that such activities should be conducted by the PV Council as these serve as a platform for all stakeholders to interact. She further emphasized that the PV Council should support healthcare professionals and patients who are the end users and are required to play important roles in PV.

Earlier, Dr J Vijay Venkatraman, Chair of ISCR’s Pharmacovigilance Council, welcomed the

gathering and elaborated on the significance of the symposium's theme. Assistant Drug Controller, Mr Somnath Basu also presented his views on the subject.

Mr John Barber, Director, Head of Pharmacovigilance – European Operations, Dr Reddy's Laboratories (UK), gave a presentation on current EU Regulations, planned changes and their impact on India. His experience threw light on how India is adopting and adapting EU guidelines. Dr S D Sinha, Vice President and Head – Global Pharmacovigilance, Clinical Development, Medical Affairs at Hetero Drugs spoke on PV of Biosimilars and discussed the ethnic differences of data, challenges and the requirement for biosimilars guidelines.

There was a panel discussion on the "PV Guidance Document for MAHs of Pharmaceutical Products" recently released by PvPI. The session was moderated by Dr P S Karthik Babu – Affiliate Pharmacovigilance Head, Sanofi, and saw representation from the CDSCO, foreign multinationals, and Indian companies who engaged in an enriching discussion on the timeframe for implementation of the guidelines, expectations, interpretations, challenges and acceptability from various sections of the audience.

The different stakeholders appreciated the efforts of the PvPI in developing the guidelines. Mr Basu concluded that the guidelines are developed for stakeholders who need to set up PV systems in their organizations and welcomed comments and suggestions from the industry, which would be incorporated in later revisions.