Highlights of the Fifth ISoP-UMC Pharmacovigilance Joint Training

The fifth ISoP–UMC pharmacovigilance joint training was successfully held in Shenyang, a city in northeast of China during January 11-12, 2018. The PV training was jointly sponsored by International Society of Pharmacovigilance (ISoP), Uppsala Monitoring Centre (UMC), and supported by International Society of Pharmacovigilance China Branch and Research Center for International Food and Drug Policies and Laws of Shenyang Pharmaceutical University. There were 53 participants mostly from Chinese drug regulatory administrations, commercial enterprises, medical institutions, and scientific research academies at all levels such as professionals and administrative staff who are engaged into pharmacovigilance, clinical research and risk-benefit evaluation.

"How does harmonization of active surveillance and signal detection evaluated by PV inspection lead to better safety governance?" was the main topic of this training. China has formally joined ICH in June 2017, and so this ISoP-UMC PV training was timely in enabling Chinese drug manufacturing enterprises, research institutions, regulatory authority to better adapt to the increasingly harmonized global regulatory environment, enhance the capacity on drug risk-benefit evaluation and risk minimization, and promote the development of pharmacovigilance technology in China.

This two day-course was conducted with PV expertise drawn from UMC & ISoP, China Food and Drug Administration (CFDA) as well as local organizations and is designed to address both practical and theoretical aspects of pharmacovigilance. Part of the training also addressed the methodologies of intensive safety monitoring and post-authorization safety studies using case studies as well as good practices for pharmacovigilance inspections. The opening ceremony was held on the morning of January 11, and Dr. Brian Edwards (Board Member and Chapters coordinator of ISoP), Dr. Pia Caduff (Chief Medical Officer of UMC) and Dir. Zhou Lingyun (Coordinator of ISoP China Chapter) jointly made opening speeches to welcome domestic and overseas participants/experts, briefly introduced the history, visions, missions and development plans of ISoP and UMC, highlighted that ISoP Headquarters and UMC will maintain close collaboration with various chapters all over the world, e.g. China chapter to jointly promote the PV training and facilitate technical exchange of Pharmacovigilance activities in China. Later, the PV experts conducted training on safety data management and exchange, signal detection analysis and management, Logical application of causality, PV inspection, Risk communication, Intensive safety monitoring programs and other topics. Training was delivered through lectures, working groups and panel discussions, for example "signal detection and management, EU/US Pharmacovigilance Inspection Regulations" (speech of Dr. Brian Edwards), " the logic of causality, signal detection principles, and communication of drugs-related risks" (speech of Dr. Pia Caduff), "Safety Data management and exchange under the global pharmacovigilance environment" (speech

of Helena Wilmar), " Industry Experience in PV inspection (global & local)" (speech of Zhang Yijing) and "Development history and practice of pharmacovigilance system in Chinese hospitals" (speech of Dr. Deng Jianxiong), Pharmacist In Charge Meng Kangkang and Chief Pharmacist Wang Dan of CFDA's Center for Drug reevaluation also delivered excellent speech on introduction of Drug Adverse Reaction Reporting and Monitoring Guidelines and interpretation on Chinese Regulations on Intensive safety monitoring. Meanwhile, the training was also conducted in the context of real world practice in China, for example more and more attention was addressed on the safety problems related to Traditional Chinese Medicine today. We invited Prof. Zhang Li from the Affiliated Dongfang Hospital of Beijing University of Chinese Medicine to give a speech about "exploration and practice of intensive monitoring modes for traditional Chinese medicine".

Finally, the training also adopted case study, small group discussion teaching modes, for example there were 4 groups split into 2 cases study (chemical drug and bio-similar product) each group selected representative to share their group discussion result on RMPs for their respective products. Brian Edwards and Pia Caduff answered questions and gave feedback on each group presentation. Participants proactively raised questions during the Q&A session. Chinese and overseas scholars freely exchanged hot topics and research progress in the field of pharmacovigilance. There was simultaneous interpretation arranged to enhance the training experience. The training was widely acknowledged and appreciated by attendances from both its content to its training mode, and participants specified that it was a fruitful training.

At the end of the training, Pia Caduff, Brian Edwards and Prof. Zhang Li jointly made a closing remark respectively on behalf of UMC, ISoP and ISoP China chapter. They emphasized again the objectives of the International Society of Pharmacovigilance to encourage the building of "high quality and scientific" international pharmacovigilance technology organizations, jointly promote the academic activities and technological development of global pharmacovigilance and guarantee public health. The ISoP China chapter also expressed that it will further enhance the communication with Headquarters and UMC, actively conduct academic activities related to pharmacovigilance in the future, and acknowledged the great support of ISoP Headquarters, UMC, CFDA experts, in ensuring the success of this joint event. This excellent ISoP-UMC joint training on pharmacovigilance provides experts and scholars from Chinese medical institutions, medical colleges, medicine scientific research institutions and pharmaceutical enterprises, an important platform for further enhancing technical exchange and information communication in the field of pharmacovigilance, guiding rational use of medicines clinically, improving clinical treatment standards, etc. It will promote the construction of pharmacovigilance technology and system in China to enhance the safe and effective use of medicines.