Drug Safety (2022) 45:699–702
https://doi.org/10.1007/s40264-022-01195-y

FROM THE ISoP

An Update on the International Society of Pharmacovigilance China Chapter

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Accepted: 30 May 2022 / Published online: 25 June 2022

1 Introduction

Pharmacovigilance (PV), an important part of drug monitoring, is one of the significant focuses of drug regulatory agencies all over the world. As a global authoritative, independent, and non-profit organization, the International Society of Pharmacovigilance (ISoP) provides researchers an open and professional platform to share experience and knowledge and to avail of affordable education and training. In order to address the needs in different countries and regions and attract more researchers to participate in PV activities, ISoP has established Chapters worldwide with support and guidance from the Executive Committee and Chapters Coordinator. The 14th ISoP Annual Meeting was successfully held in China for the first time in 2014, and then the ISoP Executive Committee officially announced the creation of the ISoP China Chapter in October 2016 at the Annual Meeting in Agra (India). To further build a bridge for communication of PV information at home and abroad, the ISoP China Chapter established its WeChat Official Account in December 2017 and published news and articles since October 2019, which strengthened public awareness of PV and ensured the safety and effectiveness of medicines for the public.

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2 Objectives and Activities of the ISoP China Chapter

The ISoP China Chapter aims to formulate an academic activity plan suitable for China and offer a PV scientific methodologies and information exchange platform [1]. After 5 years of development, the ISoP China Chapter has contributed to strengthening the PV system in China by holding regular meetings, symposia, and trainings and establishing a public social media platform. Specific achievements are summarized as follows.

2.1 Co-Sponsorship of Two Joint ISoP-Uppsala Monitoring Centre Training Courses

ISoP and the Uppsala Monitoring Centre are jointly committed to accelerating scientific research related to drug risk-benefit evaluation and risk management. The training sessions have been held seven times since 2014. China formally joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use in 2017, then the National Medical Products Administration (NMPA) issued and updated a series of PV regulations from clinical trials to post-authorization surveillance. Focusing on PV in China, the ISoP China Chapter and ISoP–UMC co-sponsored the 5th and 7th PV joint training course on the 11–12 January, 2018 and the 11–12 November, 2019, respectively, which topics are "How does harmonization of active surveillance and signal detection evaluated by PV inspection lead to better safety governance" and "Pharmacovigilance systems in China: Moving to the next step". The courses mainly discussed the practical and theoretical aspects of PV in China and the key technological problems faced throughout the whole process of risk management under the new situation [2, 3]. They have further implemented the new regulations, effectively carried out risk management practices, and enhanced PV standards and risk control abilities in China.

2.2 Publication on the Post-Authorisation Drug Evaluation and Monitoring System of the European Medicines Agency

On the occasion of the first issuance of the Chinese Good Pharmacovigilance Practice [4] on 13 May, 2021, we published a series of articles on the theme of Post-Authorisation Drug Evaluation and Monitoring System of the European Medicines Agency in one of the Chinese core scientific medical journals, *Drug Evaluation Research*. The articles covered the core areas involved in drug re-evaluation, such as post-authorization studies on efficacy, safety, and authorized drugs through expedited review approaches, additional monitoring systems, and medical literature monitoring of adverse drug reactions [5–9]. The articles established the foundation that corresponds to the technological guiding principles, improves China's post-authorization drug evaluation system, and implements Good Pharmacological Practice in the lifecycle of medicinal products.

2.3 NMPA Center of Drug Reevaluation-ISoP-UMC Symposium

The ISoP and the ISoP China Chapter collaborated with the Center of Drug Reevaluation NMPA to host Session 8 of the upcoming Pharmacovigilance Conference scheduled from 19 to 21 October, 2021, with the topic "Monitoring the safety of medicines in special populations" [10, 11]. It not only encouraged academic exchange in PV among experts and scholars from various countries, but also comprehensively presented the latest methodologies and front-line practices in safety monitoring of medicines in special populations. It has provided a great opportunity for ISoP and the Center of Drug Reevaluation NMPA to establish a close and long-term relationship.

2.4 Creation of a WeChat Official Account to Expand the Influence of ISoP

As some social media platforms such as Twitter and Facebook are unavailable in China, a WeChat Official Account of the ISoP China Chapter, named "isopchinachapter", was set up. WeChat is a new technology application that has an extremely large user base in China and can help promote the diversified development and public understanding of PV and the activities of ISoP. "Isopchinachapter" has published a total of 92 pieces of information and articles up to 30 April, 2022, including six distinct sections that translate and collate PV information from drug regulatory agencies at home and abroad. These sections involve: (1) latest developments in the field of drugs and medical devices from the official websites of NMPA, US Food and Drug Administration, European Medicines Agency, and Pharmaceutical and Medical Devices Agency; (2) coronavirus disease 2019 drug information; (3) laws and regulations newsletter on the official websites of NMPA, US Food and Drug Administration, European Medicines Agency, and Pharmaceutical and Medical Devices Agency; (4) conference and training information including global PV training courses, conference details, and special seminars; (5) a scientific literature section that mainly shares the articles related to PV in *Drug Safety* and other Chinese core scientific medical journals; and (6) other information (Table 1).

3 Cooperation and Connections Between ISoP China Chapter and Other Domestic and International Organizations

The ISoP China Chapter will continue to cooperate extensively with other organizations involved in drug evaluation and PV at home and abroad. Meanwhile, it will continue

Table 1 Summary of the WeChat "isopchinachapter"

"isopchinachapter" sections	Description
Latest developments of drugs and medical devices	NMPA drug instructions revision summary, FDA drug information, PMDA drug information, highlights of the European Committee for Medicinal Products for Human Use meetings
COVID-19 drug information	PV and clinical trial information related to COVID-19
laws and regulations newsletter	Updated summary of laws and regulations on the official websites of NMPA, FDA, EMA, and PMDA
Conference and training information	ISoP conference and training information
literature introduction	Articles related to PV in *Drug Safety* and Chinese core medicines journals
Others	An introduction about ISoP, a message from the IsoP President, an introduction to World Patient Safety Day, a statement in support of World Pharmacists Day, and the list of ISoP Fellowship Awards

COVID-19 coronavirus disease 2019, *EMA* European Medicines Agency, *FDA* US Food and Drug Administration, *ISoP* International Society of Pharmacovigilance, *NMPA* National Medical Products Administration, *PMDA* Pharmaceutical and Medical Devices Agency, *PV* pharmacovigilance

sharing information that promotes the importance of ISoP in international cooperation.

3.1 Active Participation in National Meetings

The ISoP China Chapter connects ISoP with China PV, with a goal of strengthening communication between the two parties by devoting itself to building strong connections with other academic organizations at home and abroad in tackling challenges relating to the safety and effectiveness of medicines. Therefore, a key activity of the Chapter continues to be the promotion of PV and drug risk management knowledge in academic seminars to provide a platform for researchers to interact and learn. At the same time, we have actively expanded the impact of ISoP and its official academic journal, *Drug Safety* at conferences and seminars, such as the 2nd Post-Marketing Drug Risk Assessment and Risk Management Conference and the Forbidden City International Pharmacist Conference 2021 (3–10, September) [12, 13].

3.2 Wide Participation in International Meetings

To further promote PV activities, the Chapter has actively worked with other global organizations. In December 2019, a symposium entitled "Challenges and Strategies in the Post Marketing Studies of Herbal and Traditional Medicine (HTM) Products" was proposed by the ISoP China Chapter and accepted as one of the 13 topics for the presentation at the 12th Asian Conference on Pharmacoepidemiology in Kyoto, Japan. As the first HTM presentation in both the International Society for Pharmacoepidemiology conference and the Asian Conference on Pharmacoepidemiology, the ISoP China Chapter made significant contributions to integrating HTM with modern research methods and promoting the status of HTM in the global healthcare system [14, 15].

4 Future Plans

Established in 2016, a professional team of the ISoP China Chapter has been put in place that has worked to enhance international influence and communication. To keep pace with global PV development, we will continue strategically supporting the Chinese PV system and continue improving our capabilities in the following areas.

4.1 Focus on Key Issues and Deepen International PV Co-operation

Considering the new challenges for drug research and development and the changing global environment, the Chapter will remain focused on its aims in supporting and building a platform of international PV exchange and cooperation. First, it will continue to co-sponsor and organize educational opportunities and deepen the communication with NMPA, academic institutions, and enterprises with the implementation of training programs and sharing of PV policies, methodologies, and advice. Moreover, we will assist ISoP and the newly formed Institute of Pharmacovigilance (https://pharmacovigilance.institute/) to carry out pilot work in China for the Global Pharmacovigilance Professional Certification Program to develop talent in the discipline of PV and improve recognition of PV professionals at home and abroad.

4.2 Promoting PV to the Public

The Chapter will actively promote the exchange of safety information and science to enhance public awareness of PV. First, we will promote the sharing of PV knowledge and education, while supporting the publication of PV-related books and articles based on the translation of international scholarly PV textbooks and bibliographies. In addition, the WeChat Official Account will continue to be used to provide real-time information on authoritative regulatory policies, related to PV news, and the latest developments on research. New formats will be utilized such as short videos, cartoons, and handbooks, which will enhance public awareness, participation, and support in establishing a flourishing and vibrant environment for PV in China.

Acknowledgements Thanks to Deirdre McCarthy and Mira Harrison-Woolrych for conceiving the idea on the series of articles, which inspired this one; to Deirdre McCarthy for the modification of the manuscript; to Jean-Christophe Delumeau, Brian Edwards, and Sophie Spence for their ongoing support and help on the development of the ISoP China Chapter; to Xue Tang and Lingyun Zhou for promoting ISoP activities in China; and to my team from the Beijing University of Chinese Medicine for managing the WeChat Official Account and their support on the daily work of the ISoP China Chapter.

Declarations

Funding No sources of funding were used to prepare this article.

Conflict of interest Yalu Wen, Tianyi Yang, Li Zhang, Brian Edwards, Honghui Wu, Jukai Huang, and Xiaohui Yang have no conflicts of interest that are directly relevant to the content of this article.

Ethics approval Not applicable.

Consent to participate Not applicable.

Consent for publication Not applicable.

Availability of data and material Not applicable.

Code availability Not applicable.

Author contributions All authors contributed to, edited, and approved the final manuscript.

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