International Society of Pharmacovigilance

ISoP-Asia 2013 Symposium

Pharmacovigilance Across Borders in Asia

Singapore, March 19-20-21

Venue: TUV SUD PSB Ltd. (Level 1)

1 Science Park Drive - Singapore 118221

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Programme

Day 1 Tuesday March 19	**Pharmacovigilance Centers Session**	Auditorium
08:00-08:30	*Registration*	
	Chairpersons: Mr. Antonio Mastroianni and Dr. Jean-Christophe Delumeau	
08:30-08:45	*Opening words by the Chairpersons*	
08:45-09:30	Update on the WHO Medicines Safety Programme *By Mr. Antonio Mastroianni and Ms. Helena Wilmar (WHO-UMC)*	
09:30-10:00	Report from 30 years of pharmacovigilance in Thailand *By Dr. Wimon Suwankesawong (Thai Food and Drug Administration)*	
10:00-10:30	HSA's experience in improving safety data collection and management *by Ms. Tan Wei Chuen (Health Sciences Authority, Singapore)*	
10:30-11:00	*Coffee Break*	
11:00-11:45	Data management of Individual Case Safety Reports: Points to consider *by Mr. Magnus Wallberg (WHO-UMC)*	
11:45-12:45	Panel discussion including heads of ADR Centers and presenters 1. Harmonising safety reporting requirements. Why and How? 2. Moving to an E2B system. How and Why?	
12:45-13:45	*Lunch*	
13:45-14:15	Report from the experience of the Philippines FDA with an E2B system *By Dr. Kenneth Hartigan-Go and Ms. Maria Victoria P. Calub (Philippines FDA)*	
14:15-14:45	Experience from the new PV regulation in Indonesia *By Dr. Siti Asfijah Abdoellah (National Agency of Drug and Food Control, Indonesia)*	
14:45-15:15	Pharmacovigilance system in Vietnam *By Dr. Nguyen Hoang Anh (Vietnam Center for Drug Information and ADR Monitoring)*	
15:15-15:45	Pharmacovigilance in Malaysia *By Dr. Sameerah Shaikh Abdul Rahman (Ministry of Health, Malaysia)*	
15:45-16:15	*Coffee Break*	
16:15-17:15	Panel discussion among chaired by Dr. Ian Boyd (ISoP EC member) 3. Overcoming HCPs reluctance to report ICSRa 4. Risk Minimisation measures applicable to non-ICH countries	
17:15-17:30	Concluding remarks	

ISoP gratefully acknowledges the support received from the WHO-West-Pacific Regional Office as well as the assistance received from the WHO-Uppsala Monitoring Centre as partner and co-organizer.

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Day 2 Wednesday March 20	**ISoP Lecture Session I**	Room: Theatrette
	Chairpersons: Prof. Hervé Le Louet and Dr. Kenneth Hartigan-Go	
08:30-09:15	Opening Presentation: Current trends in pharmacovigilance *By Prof. Hervé Le Louet, President of ISoP*	
09:15-10:00	Role of the new PV centre (KIDS) in the Korean PV system *By Prof. Park Byung Joo (KIDS / Seoul National University)*	
10:00-10:30	Cambodia: A ICH-aligned PV System model for developing countries *By Mr. Cheap Thonvuthy and Mr. Sea Thol (Cambodian Pharmacovigilance Centre)*	
10:30-11:00	*Coffee Break*	
11:00-12:00	Interactive panel discussion chaired by Dr. Ulrich Hagemann 1. Involving patients in pharmacovigilance 2. Methods for improving ICSR collection	
12:00-13:00	*Lunch*	
13:00-13:45	The Pharmacovigilance Programme of India (PvPI) *by Prof. Yogendra Kumar Gupta (All India Institute of Medical Sciences)*	
13:45-14:30	The Pharmacovigilance System in Taiwan By *Dr. Chen Wen Wen (Chief Taiwan ADR Reporting Centre)*	
14:30-15:15	The new European pharmacovigilance legislation and its impact in Asia *By Dr. Ulrich Hagemann, (ISoP EC member)*	
15:15-15:45	*Coffee Break*	
15:45-16:45	Panel discussion chaired by Prof. Ian Wong (ISoP EC member) 3. Legal protection for spontaneous reporters 4. Safety oversight over promotional practices	
16:45-17:00	Concluding remarks	

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Day 3 Thursday March 21	**ISoP Lecture Session II**	Room: Theatrette
	Chairpersons: Dr. Brian Edwards and Dr. Andrew Bate	
08:30-09:15	Methods for risk minimisation *By Dr. Yola Moride (ISoP EC member)*	
09:15-10:00	Methods for the detection and interpretation of signals *By Dr. Andrew Bate (ISoP EC member)*	
10:00-10:45	Methods for risk communication *By Dr. Ian Boyd (ISoP EC member)*	
10:45-11:15	*Coffee Break*	
11:15-12:15	Panel discussion chaired by Prof. Ian Wong (ISoP EC member) 1. Enforcing inspection 2. Quality-safety Interface in reference to counterfeited products	
12:15-13:15	*Lunch*	
13:15-14:00	Considering ethnic factors in pharmacovigilance *By Dr. Marco Tuccori (ISoP EC member)*	
14:00-14:45	Implementing the EU-RMP outside the EU: feasible or fantasy? *By Dr. Brian Edwards (ISoP EC member)*	
14:45-15:30	Best PV practice guidance for advanced therapy medicinal products *By Dr. Brian Edwards & Dr. Kenneth Hartigan-Go (ISoP EC members)*	
15:30-16:00	*Coffee Break*	
16:00-17:00	Interactive panel discussion chaired by Dr. Ian Boyd (ISoP EC member) 3. Avoiding bureaucracy in pharmacovigilance 4. Improving ICSR quality	
17:00-17:30	Concluding remarks. Next steps. *By the Chairpersons and Presenters*	
17:30	*End of the meeting*	

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