

Announcement

2013 APEC Harmonization Center Pharmacovigilance Workshop

20-21 November 2013, Seoul, Republic of Korea

Draft Agenda Located in page 4

BACKGROUND

The APEC Harmonization Center (AHC) is organizing the **“2013 APEC Harmonization Center Pharmacovigilance Workshop”** which will take place in Seoul, Republic of Korea on November 20-21, 2013.

Established under the authority of the Asia Pacific Economic Cooperation (APEC) and its subgroup, the Life Sciences Innovation Forum (LSIF), the APEC Harmonization Center has aimed to provide its best assistance to solve as well as to address issues related to regulatory harmonization in the field of life sciences in APEC member economies.

Following its previous sixteen successful international workshops, the third AHC workshop of 2013 on pharmacovigilance builds upon previous AHC Workshop in 2012 in Seoul, Korea.

Pharmacovigilance(PV), defined by the World Health Organization(WHO) as ‘the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems,’ plays a key role in ensuring that the patients receive safe medicinal products in the context of the benefits these products provide. Public awareness and expectations for timely and efficient safety signal detection for drugs, therapeutic biologics, and vaccines have been increasing. Therefore it is important for APEC economies to recognize the importance of pharmacovigilance which ensures the safety of the patients who receive medicinal products, and to discuss the regulatory convergence of pharmacovigilance among themselves.

As an activity of the APEC Regulatory Harmonization Steering Committee (RHSC) *Roadmap to Promote Regulatory Convergence for Pharmacovigilance*, the November 2013 workshop will be a platform to understand the importance of pharmacovigilance and the gaps and capacity of its systems in each economy. This workshop will bring together pertinent entities including regulators, industry representatives, and experts from academia to facilitate the harmonization and convergence of pharmacovigilance in APEC economies that will ultimately support harmonized and pragmatic regulatory requirements in pharmacovigilance by 2020.

The first day of the workshop will cover harmonization efforts on pharmacovigilance, including the overview of Pharmacovigilance Roadmap, and the current status and gaps of pharmacovigilance in APEC economies and issues and changes towards its harmonization. It will also touch on risk communication and current practices. The following day will have regulators only session and an optional visit at local pharmacovigilance institute in Korea.

In regards to the goal of the workshop, the APEC Harmonization Center is pleased to invite you to participate in this workshop as officials from regulatory authorities, industry representatives, and members of academia.

There is no registration fee to participate in this Pharmacovigilance Workshop; however, the space is limited so we encourage all eligible participants to register online as soon as possible. APEC economies are considered to be represented by regulators, industry representatives, and experts from academia. The latest announcement and agenda are posted on the APEC Harmonization Center website at www.apec-ahc.org. The official language of the workshop is English, and English-Korean simultaneous interpretation is only available in Korean.

WORKSHOP OBJECTIVES

This workshop is to bring together regulators, industry representatives, and experts from academia to recognize the importance of pharmacovigilance which could facilitate the harmonization and convergence of pharmacovigilance in APEC economies that will support harmonized and pragmatic regulatory requirements in pharmacovigilance by 2020. It will be the place to highlight the pharmacovigilance status in APEC economies as well as discuss the APEC RHSC PV roadmap in terms of its range, priority settlement of regulatory harmonization areas, and cooperative ways with other existing organizations such as WHO and ICH.

PARTICIPANTS

- All APEC member economies are invited to participate.
- Anticipated workshop attendees include regulators, industries, and academia.
- Travel and per diem expenses (including accommodation) will be provided for one (1) participant from the following APEC economies: Australia, Brunei Darussalam, Canada, Chile, China, Hong Kong, Indonesia, Japan, Malaysia, Mexico, Papua New Guinea, Peru, Philippines, Russia, Singapore, Chinese Taipei, Thailand, The United States and Viet Nam.

THE REPUBLIC OF KOREA VISA INFORMATION

- Visa Waiver countries (90 days): Thailand, Singapore, New Zealand, Malaysia, Peru, Mexico, Chile
- Visa Free Entry: The United States (90 days), Hong Kong China (90 days), Japan (90 days), Canada (6 months), Brunei Darussalam (30 days), Chinese Taipei (90 days), Australia (90 days)
- Visa Requirements: People`s Republic of China, Indonesia, Papua New Guinea, Russia, The Philippines, Viet Nam

If you need further information, please go to <http://www.mofat.go.kr/ENG/visa/application/>

VENUE AND ACCOMMODATION

The workshop will take place at the Grand Hilton Hotel, Seoul. Attendees are responsible for their own hotel arrangements and costs. AHC funded participants are required to stay at the designated hotel. Workshop participants should contact the hotel directly to make reservation using the following points of contact.

1. Grand Hilton Hotel, Seoul (Workshop Hotel)
Home page: <http://www3.hilton.com/en/hotels/south-korea/grand-hilton-seoul-hotel-SELGRHI/>
Address: 353 Yeonhui-ro, Seodaemun-gu, Seoul, 120-710, Korea
E-mail: Kelly Moon (skmoon@mail.grandhiltonseoul.com)
Phone: +82-2-2287-8427, +82-2-2287-8400
Cut-off Date: 13 November 2013

2. The Grand Suite, Serviced Residences (On the Grand Hilton Seoul compound)

Home page: www.grandsuite.co.kr

Address: 201-1, Hongeun-dong, Seodaemun-gu, Seoul, 120-710, Korea (Grand Hilton Seoul District)

E-mail: Kelly Moon (skmoon@mail.grandhiltonseoul.com)

Phone: +82-2-2287-8427, +82-2-2287-8400

Cut-off Date: 13 November 2013

※ Please let the hotel staff know that you are the APEC workshop participant for your reservation. Hotels will provide special rates for participants of the APEC workshop. Room reservations must be made no later than **each Cut-off Date**. After this date, any special accommodation rates may not be applied.

PARTICIPANT REGISTRATION FORM

All participants wishing to attend the workshop are required to complete the workshop registration form online only at www.apec-ahc.org (online registration will be opened on 4 November and closed on 17 November, 2013). Please keep in mind that space is limited, so participants are encouraged to submit the required Registration Form as soon as possible. Participants from APEC economies may include from regulatory agencies, industries, and academia.

ORGANIZATION

The APEC Harmonization Center is organizing the workshop.

CONTACTS

If you would like additional information please contact: APEC Harmonization Center Secretariat (ahckorea@kpma.or.kr)

2013 APEC Harmonization Center Pharmacovigilance Workshop Program

- How to Harmonize the Pharmcovigilance in APEC Region -

Day 1 (Nov. 20)			
Time	Sessions	Title	Speaker
08:00-09:00		Registration (Participants)	
09:00-09:15	Opening Ceremony	Opening and Welcoming Address	Jin Ho Wang (AHC Director)
		Congratulatory Remarks 1	Seung Jeong (Minister of MFDS)
		Congratulatory Remarks 2	Kyeong Ho Lee (Chairman of KPMA)
09:15-09:35	Keynote speech	Driving Pharmacovigilance Success	Moo-Young Yoo (Director General of Pharmaceutical Safety Bureau)
09:35-09:45		Photo Session	
09:45-10:00		Coffee break	
Session 1: Harmonization Efforts on Pharmacovigilance Co-Chairs: Byung Joo (BJ) Park (KIDS) / Wimon Suwankesawong (Thai FDA)			
10:00-10:20		APEC Efforts on Pharmacovigilance and Overview of Pharmacovigilance Roadmap	Jong-Pill Park (MFDS)
10:20-10:50	Harmonization Activities on Pharmacovigilance	WHO Activities on Pharmacovigilance	Shanthi Pal (WHO)
10:50-11:10		ICH Activities on Pharmacovigilance	Gerald Dal Pan (US FDA)
11:10-11:30		Academia's Activities on Pharmacovigilance	Ian Wong (ISoP)
11:30-12:00		Q&A and Discussion	
12:00-13:30		Lunch	
Session 2: Issues and Challenges towards Pharmacovigilance Harmonization Co-Chairs: Sunhee Lee (MFDS) / Antonio Mastroianni (UMC)			
13:30-13:40		Global Leadership for the Safer Use of Medicines	Antonio Mastroianni (UMC)
13:40-14:00	Readout of the Survey	Results from Pharmacovigilance Questionnaire of APEC RHSC	Young-Jin Ahn (MFDS)
14:00-14:50	Issues and Challenges	Regulatory's Perspective (3)	Siti Abdoellah (Indonesia), Wimon Suwankesawong (Thailand), Li Zhang (China)
		Industry's Perspective	Jean-Christophe Delumeau (Bayer)
		Academia's Perspective	Nam-Kyong Choi (SNU)
14:50-15:10		Coffee break	
Session 3: Current Status and Gaps of Pharmacovigilance System in APEC Economies Co-Chairs: Gerald Dal Pan (US FDA) / Siti Abdoellah (NADFC)			
15:10-16:40	Sharing Experiences of Pharmacovigilances	Panel Discussion: What are the Current Status and Gaps of Pharmacovigilance? - How Each Economy is Involved with WHO Monitoring Program - How Each Economy Adopts the ICH Guidelines for Pharmacovigilance - What are the Challenges and Gaps of Pharmacovigilance in Each Economy and What are the Needs to Improve/Solve Them?	Chile, China, Indonesia, Korea, Malaysia, Peru, Thailand, UMC
16:40-17:00		Coffee break	
Session 4: Plenary Lecture - Risk Communication Co-Chairs: Jin-Ho Lee (KoPERM) / Jean-Christophe Delumeau (Bayer)			
17:00-17:35		Risk Communication Introduction and Current Practices	Gerald Dal Pan (US FDA)
17:35-17:45		Q&A and Discussion	
17:45-17:55		Conclusion and Wrap-Up of the Workshop	Gerald Dal Pan (US FDA), Byung-Joo (BJ) Park (KIDS)
17:55-18:00		Closing Remarks	Jin Ho Wang (AHC Director)
18:30-20:00 Reception Hosted by AHC			
Day 2 (Nov. 21)			
Time		Title	Speaker
Regulators Only Session - Agenda Needs to be Identified Co-Chairs: Gerald Dal Pan (US FDA) / Donwoong Choi (MFDS)			
09:00-12:00			
12:00-13:00		Lunch	
Visit Korea Institute of Drug Safety and Risk Management (KIDS) and a Local Pharmacovigilance Institute			
13:30-14:30		Korea Institute of Drug Safety and Risk Management, KIDS	
15:00-16:30		Seoul National University Hospital Drug Safety Monitoring Center	