



Announcement (as of 3-1-13)

APEC Life Science Innovation Forum (LSIF) Medical Product Safety Public Awareness and “Single Point of Contact System (SPOCS)” Workshop *Building International Cooperation to Protect Patients* **Seoul, Republic of Korea, May 22 - 23, 2013** **Draft Agenda Located in Annex II**

Background

The Asia Pacific Economic Cooperation Life Sciences Innovation Forum (APEC LSIF), the APEC Harmonization Center (AHC), the APEC LSIF Regulatory Harmonization Steering Committee (RHSC), the Korea Food and Drug Administration (KFDA) and the APEC Technical Assistance & Training Facility (APEC TATF) will be collaborating in a regional public awareness program on safe medicines and medical products. Through this collaborative effort, the above listed groups invite you to participate in a workshop for government officials and relevant stakeholders covering the following two topics: 1) falsified/counterfeit medicines public awareness; and 2) establishment of an APEC “Single Point of Contacts (SPOCs)” system for cooperation on public awareness and criminal investigations of falsified medicines.

This workshop builds upon previous APEC workshops and seminars to promote safe medical products and to combat counterfeit/falsified medical products. Past APEC workshops include the September 2011 APEC Drug Safety and Detection Technology seminar that took place in Beijing, China, the February 2009 workshop in Mexico City and two 2008 seminars in Singapore. The May 2013 workshop is also an activity of the RHSC *Roadmap on Global Medical Product Quality and Supply Chain Integrity*.

There is no registration fee for participants to attend the May 22 - 23 workshop, however, space is limited, so eligible participants are encouraged to submit the registration form located on the workshop website as soon as possible. APEC economies should consider being represented from various Ministries, including regulators, customs, law enforcement, other appropriate government officials and industry representatives. Government and industry representatives from non-APEC economies are also invited to attend, pending APEC approval. The most current announcement, agenda and the registration forms can be located at the workshop website - www.APEC-AHC.org. The workshop will be held in English and interpretation will not be available.

Participants

- All APEC member economies are invited to participate.
- Government and industry representatives from non-APEC economies are also invited to attend, pending APEC approval.
- Anticipated workshop attendees include regulators, custom officials, law enforcement agencies, pharmacopeia officials, industry representatives and consumer organizations.
- Travel and per diem funding (including lodging) will be provided for up to two (2) participants from the following eleven APEC travel-eligible economies: China, Chile, Indonesia, Malaysia, Mexico, Papua New Guinea, Peru, Philippines, Russia, Thailand and Vietnam.

Contacts

If you would like additional information please contact: Jeffrey Gren, U.S. Department of Commerce (Jeffrey.Gren@trade.gov) or Jung Yoon Um, APEC Harmonization Center (sunnyum@korea.kr).

Regulatory Harmonization
Steering Committee



Life Sciences
Innovation Forum

The Republic of Korea Visa Information

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

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

Venue and Lodging

The workshop will take place at the Renaissance Seoul Hotel. Attendees are responsible for their own lodging arrangements and costs. AHC funded participants and APEC TATF funded participants are required to stay at the venue hotel. Workshop participants should contact the hotel directly to make reservation using the following point of contact.

1. Renaissance Seoul
Home page: www.renaissance-seoul.com
E-mail: Paul Shin (paul.shin@renaissancehotels.com)
Phone: 82-2-2222-8603
2. Novotel Ambassador Gangnam
Home page: www.ambatel.com/gangnam
E-mail: Chris Shin (nagsales1@ambatel.com)
Phone: 82-2-531-6666
3. Hotel Samjung Seoul
Home page: www.samjunghotel.co.kr
E-mail: Paul: Min Sook Lee (reserve@samjunghotel.co.kr)
Phone: 82-2-556-8572
4. Mercure Ambassador Gangnam
Home page: www.mercureseoul.com
E-mail: Alex Lee (sm1@mercureseoul.com)
Phone: 82-2-2050-6064
5. Ibis Ambassador Seoul
Home page: ibis.ambatel.com/seoul
E-mail: Victo Lee (mice@ambatel.com)
Phone: 82-2-3011-8105

※Please let the hotel staff know that you are the APEC workshop participant when you make reservation. Hotels may provide special rates for participants of the APEC workshop. Room reservations must be made no later than 21 April 2013. After this date, any special accommodation rates may not be applied. Additional information on lodging can be found on the workshop website - www.APEC-AHC.org.

Workshop Scope

The workshop's objectives are to:

- Share information on best practices in the APEC region and international best practices on public awareness.
- Develop an APEC Counterfeit/Falsified Medical Products Public Awareness Tool Kit.
- Share information on best practices in the APEC region and international best practices on related to use of a Single Point of Contact system for counterfeit/falsified medical products public awareness and enforcement.

- Develop an APEC Counterfeit/Falsified Medical Products Single Point of Contact Tool Kit.
- Discuss further implementation of the APEC LSIF Anti-counterfeit Medicines Action Plan.

Participant Registration Form

All government officials and industry representatives from APEC member economies wishing to attend the workshop are required to complete the workshop registration form located on the workshop website - www.APEC-AHC.org. 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 regulators, custom officials, law enforcement agencies, pharmacopeia officials, industry representatives and consumer organizations.

Organization

The APEC Harmonization Center, the Korea Food and Drug Administration, the APEC LSIF Regulatory Harmonization Steering Committee (RHSC), and the APEC Technical Assistance & Training Facility (APEC TATF) are organizing the seminar. APEC TATF is funded by the U.S. Department of State and managed by the U.S. Agency for International Development (USAID).

Nomination Procedure for Officials from APEC Economies Eligible for the Travel Support and Allowances and Expenses

Travel eligible APEC member economies are invited to nominate **two (2) participants and one (1) alternate participant**¹ for the workshop from the following APEC economies (China, Chile, Indonesia, Malaysia, Mexico, Papua New Guinea, Peru, Philippines, Russia, Thailand, and Vietnam). Funded participants should complete the Participant Profile in Annex I no later than March 1, 2013.

1. **Airfare - Two (2)** participants nominated from each travel-eligible APEC member economy will be provided with roundtrip **restricted economy class airfare** for the most direct and economical route.
2. **Per Diem Allowance - Two (2)** participants nominated from each travel eligible APEC member economy will be provided with per diem allowances and accommodation will be paid for in addition to the airfare.

Travel Undertaking

APEC TATF-funded participants will need to complete a travel undertaking that outlines the allowances and responsibilities of each travel eligible participant. **Funded participants are NOT authorized to purchase air tickets unless they have the explicit approval from the relevant authority (i.e. APEC TATF).** APEC TATF will purchase air tickets on behalf of funded travelers and any purchase made without explicit approval will not be reimbursed.

Annex I

PARTICIPANT PROFILE FORM
FOR NOMINATION FROM APEC ECONOMIES ELIGIBLE FOR TRAVEL SUPPORT
APEC Life Science Innovation Forum (LSIF) Workshop on Medical Products Safety and Public Awareness
and Establishing of a “Single Point of Contacts (SPOCs)” System
May 22 - 23, 2013
Seoul, the Republic of Korea

Travel-eligible APEC economies (China, Chile, Indonesia, Mexico, Malaysia, Papua New Guinea, Peru, Philippines, Russia, Thailand, and Vietnam,) are encouraged to use this form to nominate government officials to receive travel support. Each travel eligible economy can request up to two individuals, with a third official

¹Alternate will be able to attend the workshop on a self-funded, space available basis, and/or in the event that one of the original two participants is unable to attend.

designated as an alternate. It is recommended that nominated participants include representatives such as regulators, custom officials, law enforcement agencies, and pharmacopeia officials. Please submit nominations by **COB March 15, 2013**.

MEMBER ECONOMY/ORGANIZATION:

NOMINEE 1

Name:
Position:
Ministry:
Email:
Telephone:
Fax:

NOMINEE 2

Name:
Position:
Ministry:
Email:
Telephone:
Fax:

ALTERNATE NOMINEE 1

Name:
Position:
Ministry:
Email:
Telephone:
Fax:

Name of nominating official:
Position:
Ministry:
Email:
Telephone:
Fax:

Nomination forms should be submitted **by email** to Ms. Heather Grell (hgrell@nathaninc.com) and Ms. Shinta Manurung, (SM@apcc.org) of the APEC TATF, copying Mr. Jeffrey Gren (jeffrey.gren@trade.gov) of the U.S. Department of Commerce and Ms. Jung Yoon Um, (sunnyum@korea.kr), APEC Harmonization Center, by **March 15, 2013**.

Annex II

**APEC Life Science Innovation Forum (LSIF) Workshop on Medical Products Safety and Public Awareness
and Establishing of a “Single Point of Contact System (SPOCS)
Building International Cooperation to Protect Patients
Seoul, the Republic of Korea, May 22 - 23, 2013
Draft Agenda (as of 3/1/13)**

Day 1, Wednesday, May 22

- 8:30 - 9:00 **Welcome and Introductory Comments**
- **Kwang-Ho Lee**, APEC Harmonization Center Director
 - **World Health Organization Official** (invited)
- 9:00 - 9:30 **Keynote Address: Arun Kumar Panda** (invited), Joint Secretary, India Ministry of Health and Welfare, Topic “India’s Experience with Spurious/Counterfeit Medicines and Mitigating Activities Including the Use of Public Awareness, Testing Laboratories and Detection Technology” (invited) (possible back-up keynote speaker from WHO if Dr. Panda is not available)
- 9:30 - 9:45 **Mark Paxton**(confirmed), U.S. Food and Drug Administration, APEC Regulatory Harmonization Steering Committee Medical Product Quality and Supply Chain Integrity and Gap Analysis
- 9:45 - 10:00 **Jeffrey Gren**(confirmed), U.S. Department of Commerce, Director Office of Health and Consumer Goods, Summary of APEC LSIF Activities to Combat Counterfeit/Falsified Medicines
- 10:00 - 10:15 **Tea and Coffee Break**
- 10:15 - 11:15 **Presentations on the Importance of Medical Product Safety Public Awareness:** (Draft APEC Public Awareness Tool Kit to be provided to workshop participants prior to workshop)
Moderator:**Mick Deats, Sabine Kopp or Lembit Rago** of WHO (invited)
Panelists: a) **Dr. Paul Orhii**, Nigeria Director of NAFDAC **or Shaba Mohammed**, Nigeria, Assistant Director, Ports Inspection (Nigeria speaker confirmed), b) **Indonesia Speaker**, BPOM, National Agency for Drug and Food Control, (confirmed),c)**Ms. Hsueh Yung (Mary) Tai**, Senior Specialist, TFDA, Chinese Taipei, (confirmed), and d) **Libby Baney**, (confirmed)Representing the Alliance for Safe On-line Pharmacies (ASOP)
- 11:15 - 12:15 **Panel Discussion: Medical Product Public Awareness in APEC Economies - Case Studies and Best Practices:**
Moderator: **Jeffrey Gren**, U.S. Department of Commerce, Director Office of Health and Consumer Goods
Panelists: a) **Manzatul Azrul Azrie Bin Sulaiman** (confirmed),Director, Pharmacy Enforcement Division, Ministry of Health Malaysia, b) **Eugene Goh**, Singapore Health Sciences Authority(confirmed),to make a presentation on the Singapore counterfeit contact lens investigationand public awareness campaign; c) **Ilisa Bernstein**(confirmed),USFDA, outline of FDA new public awareness campaign related to dangers of internet drug purchases, d)**Peru DIGEMED Speaker** (invited)(a total of 3-4 total panelists are anticipated)
Question and Answer Session
- 12:15 - 1:15 **Lunch**

- 1:15 - 2:15 **Panel Discussion: Patient Organization and Industry Activities Related to Drug Safety Public Awareness**
Moderator: Jeannie Salo, Lilly and Member APEC Republic of Korea Workshop Planning Committee (confirmed)
Panelists: a) Bejon Misra, Director India Office, Partnership for Safe Medicines confirmed); **b) Abul Hashem**, Vice President Business Development, Project Hope (public awareness activities in China and India); **c) International Federation of Pharmaceutical Manufacturers Speaker (IFPMA)** (invited)
Question and Answer Session
- 2:15 - 2:45 **Overview of Draft APEC Public Awareness Tool Kit, Xuan Hao Chan, World Health Professional Alliance (WHPA)** (invited)
- 2:45 - 3:00 **Tea and Coffee Break**
- 3:00 - 4:00 **Discussion of Proposal for APEC Public Awareness Tool Kit** –Workshop attendees participate in discussion groups (tables of 10) focused on reviewing specific aspects of the draft APEC Public Awareness Tool Kit
The following moderators will lead the small groups to facilitate discussion: **1) Mark Paxton, 2) Jeannie Salo, 3) Ms. Hsueh Yung (Mary) Tai, 4) Anita Derks, 5) Rubie Mages, 6) Manzatul Azrul Azrie Bin Sulaiman, 7) Eugene Goh, and 8) Libby Baney**(additional moderators may be added based upon workshop registrations)
- 4:00 - 5:15 **Reporting of Discussion Groups on Draft APEC Public Awareness Tool Kit and General Discussion** (following the workshop, the Planning Committee will consolidate tool kit comments and prepare a revised draft that will first be sent to workshop participants for additional comments and then will be sent to the RHSC and LSIF Planning Group for endorsement)
- 5:15 - 5:30 **Concluding Comments for First Day of Workshop**
- 6:00 - 7:30 **Hospitality Reception**

Day 2, Thursday, May 23

- 8:30 - 10:15 **Presentations on the Importance of a Single Point of Contacts (SPOCs) for Medical Product Safety Case Studies and Best Practices**(Draft APEC SPOC Tool Kit to be provided to workshop participants prior to workshop)
Moderator: Aline Plancon, INTERPOL(confirmed),
Panelists: a) Thailand Speaker, Ministry of Public Health, Thai Food and Drug Administration(confirmed), **b) Mao Zhenbin**, (invited) China State Food and Drug Administration, Center for Report and Complaint; **c) Mohd Hatta Bin Ahmad**, (invited), Pharmacy Enforcement Branch, Ministry of Health, Malaysia (invited); **d) Susanne Keitel** (confirmed), Director General, European Directorate for the Quality of Medicine and Healthcare (EDQM), **e) Eric McIntosh**, Australia Therapeutic Goods Administration, Director of Enforcement (invited), **f) Mick Deats**, WHO (invited)
Question and Answer Session
- 10:15 - 10:30 **Tea and Coffee Break**
- 10:30 - 11:15 **Panel Discussion: Patient Organization and Industry Perspectives Related to Single Point of Contact System:**
Moderator: Anita Derks, Roche and Member APEC Regulatory Harmonization Steering Committee Oversight Committee
Panelists: a) Mr. Samson Chiu, Pharmaceutical Security Institute (PSI), Director, Asia-Pacific Region (confirmed); **b) industry representative** (to be determined)(3-4 total anticipated)

Question and Answer Session

- 11:15 - 12:00 **Proposal for APEC Single Point of Contact System Tool Kit - Overview of Proposal - Susanne Keitel**, Director General, European Directorate for the Quality of Medicine and Healthcare (EDQM) (confirmed)
- 12:00 - 1:00 **Lunch**
- 1:00 - 2:00 **Discussion of Proposal for APEC Single Point of Contact Tool Kit** - Workshop attendees participate in small discussion groups focused on reviewing the draft APEC Single Point of Contact Tool Kit. The following moderators will lead these small discussion groups to facilitate discussion: **1) Anita Derks, 2) Susanne Keitel, 3) Aline Plancon, 4) Samson Chiu, 5) Mick Deats (invited), 7) Mohd Hatta Bin Ahmad (invited), and 8) Eric McIntosh (invited)** (additional moderators may be added based upon workshop registrations)
- 2:00 - 3:15 **Reporting of Discussion Groups on Draft APEC Single Point of Contact Tool Kit and General Discussion** (following the workshop, the Planning Committee will consolidate tool kit comments and prepare a revised draft that will first be sent to workshop participants for additional comments and then will be sent to the RHSC and LSIF Planning Group for endorsement)
- 3:15 - 3:30 **Tea and Coffee Break**
- 3:30 - 4:30 **Discussion Future APEC Regulatory Harmonization Steering Committee Roadmap on Product Quality and Supply Chain Integrity Activities**
- 4:30 - 5:00 **Closing Comments**
- 5:00 **Workshop Concludes**