



Announcement and Invitation to Attend

APEC Life Science Innovation Forum (LSIF) Drug Safety and Detection Technology Workshop *Building International Cooperation to Protect Patients* September 27 - 28, 2011 Beijing, China

Draft Agenda Last Three Pages (Annex III)

Background

The Asia Pacific Economic Cooperation Life Sciences Innovation Forum (APEC LSIF) invites you to participate in a drug safety and detection technology workshop to take place in Beijing, China from September 27 to 28, 2011. The event partners in China are China's State Food and Drug Administration (SFDA) and the China National Institutes for Food and Drug Control (NIFDC). This APEC LSIF project is being led by the United States and China, with Singapore, Peru and Mexico as co-sponsor APEC economies.

This workshop will build upon previous APEC seminars to promote safe medicines, which have focused on cooperation and strategies to combat counterfeiting and promote the quality of medicines. In 2008 and 2009 APEC LSIF hosted three anti-counterfeit medical product and quality of medicine seminars. These seminars drew strong interest and led to cooperative activities related to combating the spread of counterfeit medicines and improving drug quality. Seminar participants included regulators, industry representatives, as well as customs, law enforcement and judicial officials. As a result of the 2008 and 2009 seminars an APEC LSIF Anti-counterfeit Medicines Action Plan was developed and endorsed by the APEC LSIF Planning Group in 2010. There will not be a registration fee for participants in the September 27 – 28 workshop, however, attendance is limited, so eligible participants are encouraged to submit the attached registration form as early as possible. Selections will be made with the objective of having as many APEC economies represented as possible, and to have a mix of regulators, customs, law enforcement, other appropriate government officials, industry representatives and representatives of detection technology vendors. The most current announcement and agenda can be located on the following website:

<http://www.nifdc.org.cn/en>

Workshop Scope

The workshop's objectives are to:

- Share information on the appropriate use of detection and prevention technologies for drug safety and quality by APEC economies;
- Prepare a publication on the use of detection technologies to make counterfeit medicines easier to detect and to reduce their presence in APEC economies; and
- Discuss implementation of the APEC LSF Anti-counterfeit Medicines Action Plan.

Participants

- All APEC member economies are invited to participate.
- Anticipated workshop attendees include regulators, custom officials, law enforcement agencies, pharmacopeia officials, industry representatives, consumer organizations and representatives of detection technology vendors.

- Travel and per diem funding (including lodging) can be provided for up to two (2) participants from the following ten APEC economies: Indonesia, Malaysia, Papua New Guinea, Philippines, Russia, Thailand, Viet Nam, Chile, Mexico and Peru.
- A limited number of participants can attend this workshop from the following non-APEC economies - Laos, Cambodia, India, Argentina, Brazil, Bolivia, Colombia, Costa Rica, El Salvador, Honduras, Nicaragua, Paraguay, Panama, Cuba and Uruguay. If the workshop registration are getting close to capacity participation from non-APEC economies may need to be closed, so participants from non-APEC economies are encouraged to complete the registration form in Annex II as soon as possible.
- **All participants** will be required to complete the registration form in Annex II.

Participant Registration Form (Annex II)

All government officials and industry representatives that meet the above criteria from APEC member economies and select non-APEC economies wishing to attend the workshop are required to complete the Registration Form in Annex II. Please keep in mind that space is limited, so participants are encouraged to submit the required Registrations Form as soon as possible. You will be notified if your registration is accepted at least six weeks before the workshop. Registration Forms will be reviewed and acceptance provided so workshop participation is balanced to insure participation by representatives from as many APEC economies as possible and to have balance for participation from regulators, custom officials, law enforcement agencies, pharmacopeia officials, industry representatives, consumer organizations and representatives of detection technology vendors.

Organization

The seminar is being organized by the United States, with local hosting assistance provided by China NIFDC. The workshop is being implemented with funding from the APEC Technical Assistance & Training Facility (APEC TATF), which is funded by the U.S. Department of State and managed by the U.S. Agency for International Development (USAID). In addition, support is provided by the U.S. Department of Commerce and China's State Food and Drug Administration (SFDA).

Contacts

Mr. Nimesh Modak - nm@apec.org

Ms. Shinta Manurung - sm@apec.org

NIFDC - APECLSIF@nifdc.org.cn

Mr. Jeffrey Gren, U.S. Department of Commerce - Jeffrey.Gren@trade.gov

APEC Secretariat - 35 Heng Mui Keng Terrace, Singapore 119616

Methodology

- **Agenda** - A draft agenda is included in Annex III. The seminar will include a combination of lecture presentations, discussions and demonstrations.
- **Evaluations** - Participants and speakers will be required to complete and return an evaluation form at the end of the seminar. Time will be allotted to completing this task at the close of the workshop. In the evaluation form, each participant will be encouraged to discuss the benefits of the workshop and make suggestions for future projects concerning the workshop subject matter.

- **Language** - The workshop will be held in English. To accommodate local China provincial officials, Chinese - English simultaneous translation will be provided as a cost-share for the workshop courtesy of China SFDA and NIFDC.

Administrative Circular

An administrative circular/travel note will be added to this announcement at a later date which will include the following:

- Information about local transportation to/from the airport in Beijing
- Venue and lodging information
- Information regarding visa requirements and entry into China

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

APEC member economies are invited to nominate **two (2) participants and one (1) alternate participant**¹ for the workshop from the following APEC economies (Indonesia, Malaysia, Papua New Guinea, Philippines, Russia, Thailand, Viet Nam, Chile, Mexico and Peru) by completing the Participant Profile in Annex 1 no later than July 26, 2011. Travel support is funded by USAID development assistance funds on the following terms:

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 flat-rate 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.

Selection of Workshop Speakers

The Project Planning Committee comprised of government and industry representatives including China, the United States, Singapore, Peru and Mexico is selecting speakers. If anyone has suggestions for speakers, please send an e-mail with the nomination to Jeffrey Gren at Jeffrey.Gren@trade.gov. The Planning Committee is seeking speakers from as many APEC economies as possible.

¹ Alternate 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.

PARTICIPANT PROFILE FORM
FOR NOMINATION FROM APEC ECONOMIES ELIGIBLE FOR TRAVEL SUPPORT
APEC Life Sciences Innovation Forum
Drug Safety and Detection Workshop
September 27 to 28, 2011
Beijing, China

Travel-eligible economies should (economies (Indonesia, Malaysia, Papua New Guinea, Philippines, Russia, Thailand, Viet Nam, Chile, Mexico and Peru) should use this form to nominate government officials to receive travel support. Each travel eligible economy can request up to two government officials, with a third official designated as an alternate. Please submit nominations by **COB July 26, 2011**.

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 Mr. Nimesh Modak (nm@apec.org) and Ms. Shinta Manurung (sm@apec.org) of the APEC TATF, copying Mr. Jeffrey Gren (jeffrey.gren@trade.org) of the U.S. Department of Commerce, copying Evelyn Loh (ejl@apec.org) of APEC Secretariat, by **July 26, 2011**.

REGISTRATION FORM
APEC Life Sciences Innovation Forum
Drug Safety and Detection Workshop
September 27 to 28, 2011
Beijing, China

All workshop participants are required to complete the below participant registration form. Please complete the below form and e-mail it to Mr. Nimesh Modak (nm@apec.org) and Ms. Shinta Manurung (sm@apec.org) of the APEC TATF, copying Mr. Jeffrey Gren (jeffrey.gren@trade.org) of the U.S. Department of Commerce and Evelyn Loh (ejl@apec.org) of APEC Secretariat, by **July 26, 2011**.

A. Participant's Information

Mr. Mrs. Ms. Dr. Prof.

Last Name: _____

First Name: _____

Organization: _____

Title: _____

Tel: _____

Fax: _____

Address: _____

Email: _____

Dietary Requests: Vegetarian Beef Free Pork Free None

DRAFT AGENDA

APEC Life Sciences Innovation Forum Drug Safety and Detection Workshop September 27 to 28, 2011 Beijing, China

September 27

- 8:30 - 9:00 Welcome and Introductory Comments
- **Mr. Shao Mingli**, Commissioner, China State Food and Drug Administration (invited)
 - Senior U.S. Food and Drug Administration Official (invited)
 - APEC LSIF Speaker
 - **Lembit Rago**, World Health Organization (WHO), Coordinator, Quality Assurance and Safety
- 9:00 - 9:30 Keynote Address – The Benefits and Limitations of Detection Technologies in Assuring Genuine Drug Products in APEC Economies (Speaker to be determined)
- 9:30 - 10:00 Speaker to be Determined - Medical Implications of Unsafe Medicines and Why Detection Technology is Important for Public Health (Speaker to be determined)
- 10:00 - 10:15 **Jeffrey Gren**, U.S. Department of Commerce, Director Office of Health and Consumer Goods and APEC Project Overseer, Summary of APEC LSIF Activities to Combat Falsified Medicines
- 10:15 - 10:30 Tea and Coffee Break
- 10:30 - 11:30 Presentations on Types of Detection Technologies Available - Paper on Detection Technologies to be provided to Workshop Participants Prior to Workshop (examples of technologies to be covered includes film coatings, nano-encryption, florescent markers, sophisticated product and packaging taggants, mass spectrophotometers, HPLC, gas chromatographs, colormetric analyses, overt and covert markings, etc.)
Frederick Fricke, Director USFDA Forensic Laboratory, and
Ms. Lim Chin Chin, Forensic Laboratory Director Singapore Health Science Authority
- 11:30 - 12:00 **Azrul Azwar**, President, ASEAN Family Practitioners' Association
Detection Technology from a Patient and Health Provider Perspective
- 12:00 - 1:00 Lunch
- 1:00 - 2:30 Panel Discussion: The Use of Detection Technologies in APEC Economies: Case Studies and Best Practices
- Moderator - **Jeffrey Gren**, U.S. Department of Commerce
 - **Professor Jin Shaohong**, China National Institutes for Food and Drug Control (NIFDC) - China Mobile Laboratories
 - **Mr. Frederick Fricke**, USFDA, Director USFDA Forensic Laboratory
 - **Patrick Lukulay**, Director of Drug Quality Inspection Program, US Pharmacopeia - US AID Supported Program - Promoting the Quality of Medicines
 - **Ms. Lim Chin Chin**, Forensic Laboratory Director and Forensic Scientist, Singapore Health Science Authority

- **Percy Alberto Ocampo Rujel**, Executive Director of the Directorate of Control and Health Surveillance, Peru
- **Professor Lin Ruichao**, China National Institutes for Food and Drug Control (NIFDC), Chief Expert on Traditional Chinese medicines Analysis, Topic of Remarks - Detection Technologies Concerning Traditional Chinese Medicines
- Mexico Speaker

Question and Answer Session

2:45 - 3:30 Coffee Break and Time to View NIFDC China Mobile Drug Detection Laboratories

3:30 - 5:00 Panel Discussion: Detection Technologies as Part of a Larger Strategy for Drug Authentication Quality

- Moderator - **Mr. Ding Jianhua**, Deputy Director of International Cooperation Department, China State Food and Drug Administration
- **Mr. Wang Lifeng**, State Food and Drug Administration Director General, Bureau of investigation and Enforcement
- U.S. Food and Drug Administration (speaker to be determined)
- **Eugene Goh**, Singapore Health Science Authority, Product Quality Sampling (PQS) Program
- **Aline Plancon**, INTERPOL, Topic – “How the scientific and international community builds bridges to combat falsified medical products”
- Customs Representative from APEC economy not listed above (insert topic)
- Pharmaceutical Security Institute (insert topic)
- **Mr. Somsak Sunthornphanich**, Thailand Ministry of Public Health, Senior Pharmacist, Bureau of Drug and Narcotics, Department of Medical Science

Question and Answer Session

5:00 Day 1 Adjourns

6:00 - 8:00 Reception Hosted by U.S. Department of Commerce and China

September 28

8:30 - 9:30 Panel Discussion: Industry Perspectives on Detection Technologies

- Moderator - To be Determined
- Pharmaceutical Security Institute
- China Generic Drug Association Representative
- Innovative Drug Firm Representative
- **David Webber**, General Director, World Self-Medication Industry (WSMI) (APEC approval pending)

10:00 - 10:30 Serialization and E-pedigree and the Benefits of Compatibility of Regulatory Requirements Panel Discussion – Early Detection and Data Collection, Speaker to be determined

10:30 - 10:45 Coffee Break

10:45 - 12:15 Panel Discussion: The Role of Serialization in the Detection and Prevention of Counterfeits (Key message – Serialization helps to protect the legitimate supply chain. This is a key area for APEC cooperation.)

- Moderator (to be determined)
- **Ulrike Kreysa**, GS1, Vice President Healthcare, Topic – “GS1 Serialization and E-pedigree Standards Activities, as an Example”

- USFDA Speaker
 - Speaker from APEC Economy Implementing Serialization and E-pedigree
 - Industry Speaker
- Question and Answer Session
- 12:15 - 1:15 Lunch
- 1:15 - 2:45 Panel Discussion - Early Detection and Data Collection
- Moderator - To be Determined
 - Speakers to be Determined (insert topic)
 - PSI Speaker (sampling)
 - FDA Speaker (WHO system)
- 2:45 - 3:00 Coffee Break
- 3:15 - 4:45 Concluding Session – Ensuring a Holistic Strategy for Improving Drug Quality
- Moderators - **Dr. Li Bo**, Deputy Director of NIFDC and **Jeffrey Gren**, U.S. Department of Commerce, Director Office of Health and Consumer Goods and APEC Project Overseer
 - Developing Report on Available Detection Technologies and Best Use
 - Further Implementation of the APEC LSIF Anti-counterfeit Medicines Action Plan
 - The Benefits of Public
 - Private Partnerships
 - Global Cooperation
- 4:45 - 5:00 Concluding Comments
- **Lembit Rago**, World Health Organization (WHO), Coordinator, Quality Assurance and Safety
 - Senior U.S. Food and Drug Administration Official
 - **Mr. Li Yunlong**, Director General NIFDC