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**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**

**Day 1, Wednesday, May 22**

- 8:30 - 9:00 **Welcome Comments - Jin-Ho Wang**, APEC Harmonization Center Director  
**Congratulatory Message – Byung-Won Jang**, Vice Minister of Ministry of Food and Drug Safety  
**Introductory Comments - Mark Paxton**, U.S. Food and Drug Administration
- 9:00 - 9:15 **Summary of APEC LSIF Activities to Combat Counterfeit/Falsified Medicines**  
**Speaker: Jeffrey Gren**, U.S. Department of Commerce, Director Office of Health and Consumer Goods,
- 9:15 - 9:30 **Medical Product Quality and Supply Chain Integrity and Gap Analysis**  
**Speaker: Mark Paxton**, U.S. Food and Drug Administration, APEC Regulatory Harmonization Steering Committee
- 9:30 - 10:40 **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: Mark Paxton**, U.S. Food and Drug Administration,  
**Panelists: a) Shaba Mohammed**, Nigeria, Assistant Director, Ports Inspection, **b) Retno Tyas Utami**, Deputy for Therapeutic Product, Narcotic, Psychotropic and Addictive Substance Control, National Agency for Drug and Food Control (NADFC), Indonesia, and **c) Libby Baney**, Executive Director, Alliance for Safe On-line Pharmacies (ASOP)  
**Question and Answer Session**
- 10:40 - 10:55 **Tea and Coffee Break**
- 10:55 - 12:05 **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**, Director, Pharmacy Enforcement Division, Ministry of Health Malaysia, **b) Eugene Goh**, Singapore Health Sciences Authority, to make a presentation on the Singapore counterfeit contact lens investigation and public awareness campaign; **c) Yuwadee Patanawong**, Thailand, Ministry of Public Health, Thai Food and Drug Administration, **d) Ms. Hsueh Yung (Mary) Tai**, Senior Specialist, TFDA, Chinese Taipei  
**Question and Answer Session**
- 12:05 - 1:05 **Lunch**



- 1:05 - 2:10 **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  
**Panelists:** a) Bejon Misra, Director India Office, Partnership for Safe Medicines b) Abul Hashem, Vice President Business Development, Project Hope (public awareness activities in China and India) (due to a last minute problem Abul Hashem was not able to attend, but his presentation is included in the workshop downloads) and c) Simon Collier, Senior Director, Head of Government Relations, Eisai, (Representing International Federation of Pharmaceutical Manufacturers - IFPMA)  
**Question and Answer Session**
- 2:10 - 2:30 **Overview of Draft APEC Public Awareness Tool Kit**  
**Speaker:** Simon Collier, Senior Director, Head of Government Relations, Eisai, (Representing International Federation of Pharmaceutical Manufacturers)
- 2:30 - 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 8) 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) Manzatul Azrul Azrie Bin Sulaiman, 4) Simon Collier, 5) Libby Baney, 6) Bejon Misra, 7) Anita Derks and 8) Retno Tyas Utami
- 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 (Jeff)**
- 6:00 - 7:30 **Hospitality Reception**

## Day 2, Thursday, May 23

- 8:30 - 9:15 **Public Awareness in the Age of the Internet - The Threat of Illegal Online Drug Sellers**  
**Speaker:** Libby Baney, Executive Director, Alliance for Safe On-line Pharmacies (ASOP),
- 9:15-10:00 **Panel Discussion: Presentations on the Importance of a Single Point of Contacts (SPOCs) for Medical Products**  
(Draft APEC SPOC Tool Kit to be provided to workshop participants prior to workshop)  
**Moderator:** Anita Derks, Roche and Member APEC Regulatory Harmonization Steering Committee Oversight Committee  
**Panelists:** a) Aline Plancon, INTERPOL, b) Mr. Samson Chiu, Pharmaceutical Security Institute (PSI), Director, Asia-Pacific Region c) Matthias Stacchetti, Penal Division within Swissmedic's Legal Affairs Department d) Retno Tyas Utami, Deputy for Therapeutic Product, Narcotic, Psychotropic and Addictive Substance Control, National Agency for Drug and Food Control (NADFC), Indonesia and e) Stephen Hawgood, Regional Compliance Manager, Eli Lilly  
**Question and Answer Session**
- 10:00 - 10:20 **Tea and Coffee Break**
- 10:20 - 11:45 **Panel Discussion: Presentations on the Importance of a Single Point of Contacts (SPOCs) for Medical Products (Continued)**

## **Question and Answer Session**

- 11:45 - 12:15 **Proposal for APEC Single Point of Contact System Tool Kit - Overview of Proposal**  
**Speaker: Matthias Stacchetti**, Penal Division within Swissmedic's Legal Affairs Department
- 12:15 - 1:15 **Lunch**
- 1:15 - 2:30 **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) **Matthias Stacchetti**, 2) **Jeffrey Gren**, 3) **Stephen Hawgood**, and 4) **Libby Baney**
- 2:30 - 3:30 **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)
- 3:30 - 3:45 **Tea and Coffee Break**
- 3:45 - 4:45 **Discussion Future APEC Regulatory Harmonization Steering Committee Roadmap on Product Quality and Supply Chain Integrity Activities**
- 4:45 - 5:00 **Closing Comments**
- 5:00 **Workshop Concludes**