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Economic Cooperation

APEC LSIF Anti-counterfeiting Medical Product and Pharmaceutical Product Safety Seminar: Building International Cooperation to Protect Patients

17-19 February 2009, Mexico City

APEC Life Sciences Innovation Forum

APEC Committee on Trade and Investment

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APEC LSIF Anti-Counterfeiting Medical Product and Pharmaceutical Product Safety Seminar: *Building International Cooperation to Protect Patients*

Final Report & Proceedings

APEC Life Science Innovation Forum

APEC Committee on Trade and Investment

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FINAL REPORT

APEC LSIF Anti-Counterfeiting Medical Product and Pharmaceutical Product Safety Seminar: *Building International Cooperation to Protect Patients*

I. Summary and Background:

This seminar was jointly organized by the USFDA and USDOC. Over 100 participants attended the seminar from 10 APEC economies (Mexico, Chile, Peru, the United States, Indonesia, Malaysia, Singapore, Vietnam, Philippines, and China) and six non-APEC Latin American countries (Brazil, Argentina, El Salvador, Honduras, Panama, and Uruguay).

The seminar included presentations (http://www.amcham.com.mx/Envios/Invitacion/Invitacion.htm) and panels related to the global counterfeit medical products problem including 1) how APEC economies combat counterfeit medical products, 2) the importance of intra government coordination, 3) industry perspectives on the counterfeit medical products problem, 4) the international and public health aspects of the counterfeit medical products problem, 5) quality of medicine activities and mobile laboratory detection of counterfeit medicines, 6) the role of the judiciary and law enforcement, and 7) public awareness.

The Mexico City seminar was the third seminar in a series of seminars funded by the APEC Life Science Innovation Forum (LSIF). The first two seminars took place in Singapore (January and March 2008). The findings of the first two Singapore seminars were presented to APEC Ministers during the August 2008 LSIF annual meeting in Peru.

The findings and action plans developed during the Mexico City seminar will be presented to APEC Ministers during the LSIF annual meeting during July 2009 in Singapore.

II. Development of Action Plans:

The seminar participants were divided into the following three breakout sessions - 1) criminal investigation, 2) penalties and legislation, and 3) public awareness.

Below are the major finding of each breakout session:

A. Criminal Investigation:

- Agreement was reached that all APEC economies do not have sufficient resources for effective criminal investigation and prosecution of medical product counterfeiters. Agreement was also reached that there needs to be

more effective communication between law enforcement stakeholders, and that improvement will lead to better criminal investigation results.

- The participants in this breakout group also agreed that industry and government cooperation would be useful and that future APEC training on cooperation of industry, customs and law enforcement officials was recommended.

- Participants also agreed that it is very important for each APEC economy to establish a single point of contact (SPOC) for criminal investigations.

B. Penalties and Legislation:

- Agreement was reached that a study of the extent of the existence of counterfeit medicines and counterfeit medical product activities within APEC economies would be useful. This study should be conducted by an academic, with input from health professionals, government officials, industry and NGOs.

- Participants also agreed that APEC should develop a common definition for counterfeit medical products for the purpose of this study. It was recommended that APEC use the 1992 WHO definition with the addition of including medical devices.

- The participants also agreed that there should be harmonized legislation and penalties for prosecuting medical product counterfeiters within APEC economies. There was also recognition that there may be differences in approaches to legislation and penalties based upon regional or country differences.

- The participants also agreed that WHO IMPACT guidance documents would be a useful starting point in developing harmonized penalties and legislation.

C. Public Awareness:

- Participants agreed to endorse the recommendations from the March 2008 Singapore seminar.

- Participants also agreed that APEC should conduct a study on counterfeit medicines sold on internet sites including both APIs and formulations.

- The participants also agreed to finish the additions to the communication and public awareness action plan by the end of June. USFDA agreed to serve as the coordinator for this effort, and participants from Brazil, Argentina and Peru volunteered to lead on various portions of the action plan.

- The revised action plan will include education campaigns for consumers and health professionals.

III. Next Steps and Future APEC Anti-counterfeit Medical Products Activities:

During the concluding session of the seminar the activities of a possible future APEC project was discussed. Agreement was reached that the next APEC project should focus on specific activities, rather than on a seminar with broad coverage. As was the case for the previous APEC anti-counterfeit projects, we anticipate requesting an APEC waiver to enable key non-APEC economies to be invited since the global counterfeit medical products problem is not limited to the APEC region.

Below is a listing of possible future APEC activities discussed during the concluding session of the seminar:

- A focused workshop on mobile laboratory detection for counterfeit medicines. China proposed to host this workshop at Peking University.

- A workshop focused on the regulation of APIs and activities to stop the transshipment of APIs globally that are used in the production of counterfeit medicines.

- A workshop focused cooperation between law enforcement, customs and industry on counterfeit medicine criminal investigations. A possible location for this seminar is the new Korea APEC Regulatory Harmonization Center.

- A workshop focused on establishing counterfeit medical product single points of contact for enforcement and public awareness. A possible location for this seminar is the new Korea APEC Regulatory Harmonization Center.

- A workshop focused on public awareness of counterfeit medical products. Peru offered to host this workshop.

- Funding to conduct a study of the extent of the existence of counterfeit medicines and counterfeit medical product activities within APEC economies. This study should be conducted by an academic, with input from health professionals, government officials, industry and NGOs.

- Funding to conduct a study on the extent of the impact of counterfeit medicines entering APEC economies through internet sites, including both dosage form medicines and APIs.

IV. Summary of Participants Evaluation of the Seminar

Following the seminar, participants were asked to fill out a brief evaluation form capturing their thoughts of the event. The analysis of these evaluation forms provides productive feedback as well as guidance for future events. In total, 50 evaluations were received, of which 34% identified themselves as health regulators.

There was a large representation of APEC economies at the seminar. Evaluation forms were received from participants from the following countries: Argentina,

Brazil, Chile, China, European Union, Honduras, Indonesia, Malaysia, Mexico, Panama, Peru, Singapore, Uruguay, United States and Viet Nam. 38% of the evaluation forms were submitted by participants from Mexico, suggesting that Mexico had the highest attendance rate of any of the countries represented.

80% of the participants who completed the evaluation reported that they had not attended either of the first two workshops held in 2008 in Singapore; however, 76% rated the seminar either "Excellent" or "Very Good," and 18% rated it "Good."

When asked to rate the best aspect of the seminar, 48% of those who completed the evaluation selected the format of the event, which "allowed for active discussion**,"** "Effective forum for interaction" or "Group Discussions." Other highly rated elements of the seminar included the trainers' expertise and knowledge, the ability of government officials to meet experts, and providing a good opportunity to network.

Participants were also asked to provide suggestions on future seminars. The most common response received was a request for more time to work in breakout groups. Other suggestions included increased participation of judicial and political authorities and the request for handouts and presentations to be conducted only in English, as opposed to both English and Spanish.

Agenda - 2/11/09
Asia Pacific Economic Cooperation, Life Sciences Innovation Forum Anti-Counterfeiting Medical Product and Pharmaceutical Product Safety Seminar: *Building International Cooperation to Protect Patients*
February 17 - 19, 2009, Mexico City, Mexico

Secretaría de Relaciones Exteriores (Foreign Relations Ministry)
Av. Juárez No. 20, Col. Centro 06010, México, D.F.

(Note: Most participants will be staying at the Sheraton Centro Historico in Mexico City; however, the seminar will take place at the Mexico Foreign Relations Ministry. This is a short walk from the hotel and there will be staff with signs in the hotel lobby to direct participants how to walk to the seminar.)

Tuesday, February 17

8:00 - 9:00 a.m.	**Registration and Check-In**
9:00 - 9:55	**Welcome and Opening Remarks** ***Ambassador Rogelio Granguillhome Morfin,*** Head of the Office of Economic Relations and International Cooperation, Ministry of Foreign Affairs ***Miguel Ángel Toscano Velasco,*** Mexico Ministry of Health, Federal Commissioner of COFEPRIS, (Federal Commissioner of (Federal Commission for the Protection from Sanitary Risks) ***Lic. Jorge Amigo Castañeda***, Director of the Mexico Patent and Trademark Office (IMPI) ***Paul Seligman,*** Director of Latin America Regional Office, U.S. Food and Drug Administration ***Jim Williard,*** Acting Deputy Chief of Mission, U.S. Embassy, Mexico City ***Speaker,*** American Chamber of Commerce of Mexico
9:55 - 10:00	**Five minute break -- please remain seated**
10:00 - 10:30	Summary of Asia APEC Seminars and WHO International Medical Products Anti-Counterfeiting Task Force (IMPACT) ***Valerio Reggi***, Executive Secretary, International Medical Products Anti-counterfeiting Task Force (IMPACT), WHO

10:30 - 11:30	Examples of How APEC Economies Combat Counterfeit Medical Products ***Elizabeth Carmelino García***, Executive Director, Control and Sanitary Vigilance, DIGEMID, Peru ***Raúl Chavarría Salas,*** Mexico Sanitary Promotion Commissioner ***Wan Hamid Wan Ibrahim,*** Deputy Director of Enforcement (Operations), Ministry of Health, Malaysia
11:30 - 11:45	**Coffee Break**
11:45 - 12:30	How APEC Economies Combat Counterfeit Medical Products (Continued) **Kelvin Tan,** Deputy Director, Enforcement Branch, Health Products Regulation Group, Singapore Health Sciences Authority Q and A Session
12:30 - 1:00	***Jim Thomson,*** Chair, European Alliance for Access to Safe Medicines, Partnership for Safe Medicines - Proposal for Expanded Latin American Participation
1:00 - 1:30	**Group Photo**
1:30 - 2:30	**Lunch**
2:30 - 4:30	**Panel Discussion: Importance of Intra-Government Collaboration to Detect and Deter the Counterfeiters - Regulatory, Enforcement and Judicial Aspects** **Moderator:** to be determined ***Tom Kubic***, President, Pharmaceutical Security Institute ***Paul Seligman,*** Director of Latin America Regional Office, U.S. Food and Drug Administration ***Valerio Reggi***, Executive Secretary, International Medical Products Anti- Counterfeiting Task Force (IMPACT), WHO ***Ramiro Esquivel,*** Prosecutor on Intellectual Property Rights from the Attorney General's Office, Panama
4:30 - 4:45	**Coffee Break**
4:45 - 5:15	***Jeffrey Gren***, Director Office of Health and Consumer Goods, Manufacturing and Services, U.S. Department of Commerce, International Trade Aspects of the Counterfeit Medicines Problem

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Wednesday, February 18

9:30 - 11:00 a.m.	**Panel Discussion: Industry Perspectives**

	Moderator: ***Lew Kontnik,*** Director of Brand Protection, Amgen Inc, Vice-chair PhRMA Anti-counterfeiting Working Group ***Tom Kubic****,* President, Pharmaceutical Security Institute, Pharmaceutical Industry Perspective ***Scott Miller,*** Director, Global Trade Policy, Procter & Gamble, Consumer Health Products Industry Perspective ***Leon Atencia,*** Director Latin American Regulatory Affairs, Amgen ***Thomas Warren,*** Director, Health Policy Johnson & Johnson Government Affairs & Policy, Medical Devices Industry Perspective
11:00 - 11:15	**Coffee Break**
11:15 - 1:00	**Panel Discussion - Quality Medical Products** **Moderator: Jeffrey Gren,** U.S. Department of Commerce ***Tom Layloff****,* Principal Quality Assurance Advisor, Supply Chain Management System, Arlington, VA, USA, Pharmaceutical Supply Chain Issues, E-Pedigree, and Insuring Quality Pharmaceutical Ingredients ***Prof. Shaohong Jin****,* Executive Director, National Institute for Control of Pharmaceuticals and Biological Products, People's Republic of China, Success Story - China Counterfeit Medicine Detection Program ***María José Sánchez,*** General Coordinator, ANMAT, Argentina, Example of Argentina's Counterfeit Medicine Detection Program
1:00 - 1:30	**Breakout Sessions - Overview and Instructions** ***Valerio Reggi****,* Executive Secretary, IMPACT, WHO
1:30 - 2:30	**Lunch Break**
2:30 - 4:30	**Panel Discussion - The Role of the Judiciary and Law Enforcement in Stopping the Spread of Counterfeit Medical Products and Prosecuting Counterfeiters** **Moderator:** ***Valerio Reggi****,* Executive Secretary, IMPACT, WHO ***Jose Antonio Villamil,*** Director of the Patent Division of Uruguay´s Intellectual Property Directorate ***Patrick Ford,*** Senior Director Americas Region, Global Security, Pfizer Inc. ***Lucy Delgado,*** Criminal Lawyer, DIGEMID, Peru
4:30 - 4:45	**Coffee Break**
4:45 - 6:30	**Panel Discussion - Educational Efforts to Stop the Spread of Counterfeit Medical Products (public awareness campaigns,**

efforts to educate consumers on the dangers of purchasing drugs through the internet, role of health professionals)

Moderator: ***Jim Thomson,*** Chair, European Alliance for Access to Safe Medicines
Valerio Reggi, Executive Secretary, IMPACT, WHO
Industry Speaker
Maristela Almeida, Management of Quality Monitoring, Control and Inspection of Supplies, Medicines and Products Unit, Brazilian National Health Surveillance Agency (ANVISA)
Eric Conte, Director of the Drugs and Pharmacy Department of the Ministry of Health, Panama

7:30 - 9:30 **Hospitality Reception -** Hotel Sheraton Centro Histórico, Av. Juárez No. 70, Col. Centro, C.P. 06010, México, D.F., Room - Don Diego I

Thursday, February 19

Breakout sessions will be divided into two smaller workgroups that will develop action plans to be implemented by APEC economies based upon recommendations of the two Asia seminars. Sessions run concurrently offering participants the opportunity to contribute to two breakout group. Participants will build upon the recommendation of the January and March 2008 APEC funded Asia (Singapore) seminars. Recommendations from the Asia seminar will be provided to Latin American seminar participants.

9:30 - 11:15 a.m. **First Set of Breakout Sessions:**

A. Criminal Investigation - Development of Action Plans on How Law Enforcement, Customs, and Regulators Can Cooperate (both within each APEC economy and among APEC economies) to Prosecute and Stop the production of Counterfeit Medical Products.
Moderator: ***Tom Kubic***, President, Pharmaceutical Security Institute
Co-moderator: ***Lucy Delgado,*** Criminal Lawyer, DIGEMID, Peru

B. Penalties and Legislation - Development of Actions Plans on Developing Deterrent Penalties, and Legislation to Provide Custom and Law Enforcement Officials the Tools to Stop Counterfeiters.
Moderator: ***Maria Beatriz Dellore,*** Regional IP Specialist for Latin America, U.S. Consulate General - Rio de Janeiro

U.S. Patent and Trademark Office
Co-moderator: ***Kelvin Tan,*** Deputy Director, Enforcement Branch, Health Products Regulation Group, Singapore Health Sciences Authority

C. **Communications and Detection -** Development of Action Plans on Communication to Educate Stakeholders on the Dangers of Counterfeit Medical Products, Detection of Counterfeit Medical Products by Identifying Legitimate and Falsified Medical Products, and on the Use of the WHO Rapid Response Database.
Moderator: ***Valerio Reggi,*** Executive Secretary, WHO IMPACT, WHO
Co-moderator: ***Jim Thomson,*** Chair, European Alliance for Access to Safe Medicines

11:15 - 11:30 **Coffee Break**

11:30 - 1:30 **Second Set of Breakout Sessions:**

A. Criminal Investigation - Development of Action Plans on How Law Enforcement, Customs, and Regulators Can Cooperate (both within each APEC economy and among APEC economies) to Prosecute and Stop the production of Counterfeit Medical Products
Moderator: ***Tom Kubic***, President, Pharmaceutical Security Institute
Co-moderator: ***Lucy Delgado,*** Criminal Lawyer, DIGEMID, Peru

B. Penalties and Legislation - Development of Actions Plans on Developing Deterrent Penalties, and Legislation to Provide Custom and Law Enforcement Officials the Tools to Stop Counterfeiters
Moderator: ***Maria Beatriz Dellore,*** Regional IP Specialist for Latin America, U.S. Consulate General - Rio de Janeiro U.S. Patent and Trademark Office
Co-moderator: ***Kelvin Tan,*** Deputy Director, Enforcement Branch, Health Products Regulation Group, Singapore Health Sciences Authority

C. **Communications and Detection -** Development of Action Plans on Communication to Educate Stakeholders on the Dangers of Counterfeit Medical Products, Detection of Counterfeit Medical Products by Identifying Legitimate and

	Falsified Medical Products, and on the Use of the WHO Rapid Response Database. **Moderator:** ***Valerio Reggi,*** Executive Secretary, IMPACT, WHO **Co-moderator:** ***Jim Thomson,*** Chair, European Alliance for Access to Safe Medicines
1:30 - 2:30	**Lunch Break**
2:30 - 3:30	Presentation of Action Plans from Breakout Group Moderators
3:30 - 3:45	**Coffee Break**
3:45 - 5:15	**Open Discussion/Next Steps** • Summary • Action Plan • Relationship with WHO IMPACT
5:15 - 5:30	**Concluding Comments and Adjournment**