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Update on Progress Implementing the LSIF Anti-Counterfeit Medicines Action Plan

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Update on Progress Implementing the LSIF Anti-Counterfeit Medicines Action Plan

APEC LSIF Planning Group Meeting
January 30, 2013
Jakarta, Indonesia

Presented by:
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Presentation Outline

- APEC LSIF Anti-counterfeit Medicines Initiatives and Action Plan (Part of RHSC Supply Chain Roadmap)
- APEC LSIF Drug Safety and Detection Technology Workshop - September 2011, Beijing, China
- India Patient Safety and Drug Detection and Authentication Technology Workshop, September 2012, New Delhi, India
- Plans for May 22 - 23, 2013 LSIF RHSC Drug Safety Public Awareness and Single Point of Contact (SPOC) Workshop, Republic of Korea
- Summary and Conclusion

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APEC LSIF Falsified/Anti-counterfeit Medical Product Initiatives and Action Plan

- During 2008 & 2009 APEC LSIF organized three medical product safety anti-counterfeit/falsified medicine seminars
- An APEC "Anti-counterfeit Medicines Action Plan" was developed based upon feedback during these seminars that has been endorsed by the APEC LSIF Planning Group (9/2010)
- The Anti-counterfeit Medicines Action Plan has been incorporated into the RHSC Supply Chain Roadmap
- The first workshop implementing this Action Plan (on the use of drug detection technologies) took place in Beijing September 2011 and the second workshop (with a focus on public awareness and single point of contact) will take place during May 2013 in the Republic of Korea

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APEC LSIF Drug Safety and Detection Technology Workshop – Beijing, China, September 2011

- The APEC LSIF Drug Safety and Detection Technology Workshop, took place in Beijing on September 27 and 28, 2011
- This workshop was very successful and included over 200 participants, including 100 China officials and 100 international officials
- China's State Food and Drug Administration (SFDA) and China's National Institutes for Food and Drug Control (NIFDC) were exceptional partners in organizing this workshop
- Beijing workshop results included a) enhanced APEC cooperation, b) development of a guidance document on the use of drug detection technologies, c) the development of an APEC best detection technologies practices document and d) recommendations to the APEC LSIF RHSC for future activities (these documents are handouts)

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Guidance Document On The Use Of Detection Technologies

- The use of drug detection technologies alone is not a silver bullet and must be used in a coordinated manner with regulators, customs & law enforcement, vendors and industry working together to have meaningful results
- The detection technology overview and guidance document should be updated annually to reflect advances in technologies and best practices
- There is a wide range of technologies available to APEC economies to detect falsified/counterfeit medicines
- Each detection technology adds value to the ability of an APEC economy to distinguish between authentic and falsified/counterfeit medicines

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Guidance Document On the Use of Detection Technologies

- APEC economies that have forensic laboratories with sophisticated detection technology equipment (such as the U.S. and Singapore), should share expertise
- Mobile laboratories present an effective resource for large economies, but they are expensive to purchase and maintain
- Those APEC economies with mobile laboratories (China and Russia) should share best practices
- By working with pharmaceutical manufacturers to verify information on the packaging of a suspect medicine, such as place of manufacture, lot/batch number and expiry date, APEC economies can enhance their ability to identify counterfeit/falsified medicines

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Guidance Document On The Use Of Detection Technologies

- Pharmaceutical manufacturers (innovative drugs, generic drugs and OTC medicines) should all be involved and share information on their use of detection technologies
- Pharmaceutical manufactures should also provide samples (both finished dosage form and standards used by labs for testing) for authentication purposes to drug authorities
- The use of detection technologies should not be limited to dosage form medicines and should include APIs, excepients and biologics
- Serialization is an important related topic and more work needs to be done to ensure APEC compatibility and building on best practices

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Guidance Document On The Use Of Detection Technologies

- An additional APEC detection technologies workshop should be planned within the next two years to build upon the information exchange and best practices covered during the September 2011 workshop
- The role of detection technologies at the patient and health professional level is also important and this needs further exploration.
- The use of detection technologies related to counterfeit/falsified medical devices should be explored
- Guidance provided for APEC economies, including all APEC-sponsored events, should be vendor neutral

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Korea May 22 - 23 LSIF RHSC Drug Safety Public Awareness and SPOC Workshop

- During the September 2011 LSIF Regulatory Harmonization Steering Committee meeting in San Francisco a "Concept Note" focused on drug safety and security public awareness and the development of an APEC single point of contact (SPOC) system was reviewed and endorsed
- This workshop is now being funded, with US AID and AHC support, to take place in the Republic of Korea May 22 - 23, 2013 (the workshop announcement is included in the handouts)
- This workshop will focus on medical product safety (medicines and medical devices) public awareness and the development of a Single Point of Contact System (SPOC) within APEC

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Korea May 22 - 23 LSIF RHSC Drug Safety Public Awareness and SPOC Workshop

- The prime goal of the Korea workshop is to gain adoption of public awareness and single point of contact (SPOC) APEC tool kits and to document best APEC and global public awareness and SPOC practices
- The Korea Project Planning Committee is currently working on developing these tool kits which will be reviewed by the RHSC Supply Chain Oversight Committee, before they are distributed to delegates in advance of the workshop
- During the workshop participants will break into smaller groups for interactive discussion on both tool kits and following the workshop both tool kits will be reviewed by the RHSC Supply Chain Oversight Committee and endorsed as APEC LSIF documents

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India Patient Safety and Drug Detection and Authentication Technology Workshop

- An outcome of the APEC Beijing Detection Technology workshop was planting the seed for a similar India workshop
- Dr. Arun Panda, Joint Secretary of the India Ministry of Health and Welfare, was a speaker for the Beijing workshop
- Based upon discussions with Dr. Panda, WHO and Jeffrey Gren in Beijing, agreement was reached to work to organize a international detection technology workshop in India, based upon the Beijing model, during September 2012
- After significant work, the India workshop took place in New Delhi, India on September 10 - 11, 2012

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India Patient Safety and Drug Detection and Authentication Technology Workshop

- The India workshop included about 100 India government officials, about 50 India industry reps and about 50 international government and industry reps
- There was frank and robust discussion and there was strong support by all participants for India to improve the use of drug detection technologies with emphasis on India State government involvement
- The concluding session led by Dr. Panda, develop a long and impressive list of follow-up recommendations (the top 10 recommendations are on the next two slides – the full list is a handout)

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India Drug Detection Technology Workshop – Follow-up Examples (Top 10)

1) The Government of India (GoI) has proposed a new initiative of setting up a Central Procurement Agency called "Central Medical Service Society"
2) The GoI has agreed to provide additional funds to the State governments to strengthening their regulatory mechanisms with additional staff and equipment, training, and increasing the number of laboratories
3) GoI should expedite "track and trace" technologies to ensure a safe drug supply chain. The technology to be selected should be vendor neutral, simple in implementation and affordable, especially for the small scale manufacturers

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India Detection Technology Workshop – Follow-up Examples (Top 10)

4) Service providers and the patient groups shall play a major role in educating consumers about spurious and not of-standard quality drugs with GoI support
5) There should be a "Centralized Data Bank" posted on a website on a regular basis for all information relating to approved/banned/recalled drugs
6) India industry associations, both big and small, should commit themselves to quality with appropriate self regulations
7) Department of Consumer Affairs of GoI should allocate substantial resources for creating patient safety public awareness by organizing public awareness workshops at state and regional level

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India Detection Technology Workshop – Follow-up Examples (Top 10)

8) The penalties to offenders involved in spurious drugs should be enhanced sufficiently to act as a strong deterrent

9) The GoI should provide 50 mobile laboratories for the 35 India States and Union Territories. There is also a proposal to provide hand held instruments for on the spot testing of drugs through rapid testing instruments.

10) Presently, the Drugs and Cosmetics Act does not cover standards for drugs for exports. This aspect of India law is being addressed in proposed amendment of the Act under consideration

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Conclusion and Summary

- During my presentation I covered the following topics:
  - APEC LSIF Anti-counterfeit Medicines Action Plan (part of RHSC Supply Chain Roadmap)
  - APEC LSIF Beijing 2011 Drug Safety and Detection Technology Workshop
  - India 2012 Patient Safety and Drug Detection and Authentication Technology Workshop
  - Upcoming May 2013 Korea LSIF RHSC Drug Safety Public Awareness and Single Point of Contact (SPOC) Workshop

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Conclusion and Summary

- APEC LSIF is a leader in global efforts to combat unsafe medical products including falsified/counterfeit medical products
- The RHSC Roadmap on Global Medical Product Quality and Supply Chain Integrity, the A/C Action Plan and the plan to develop medical product safety Public Awareness and SPOC Toolkits are examples of this leadership
- A priority of the RHSC flowing from the Jakarta meeting will to be to launch an expanded RHSC website. This would include the Supply Chain roadmap. The link will be www.apec-rhsc.org

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