Update of AHC Activities

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Overview of 2012 Activities

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Overview of 2012 Activities

Hosted 4 international workshops

• Biosimilar Workshop
• AHC/RHSC Awareness Workshop
• Pharmacovigilance Workshop
• Medical Device Combination Product Workshop

Invited regulators and delegates

• 39 delegates
• 11 economies

Provided information through AHC Website

• Shared training materials & video recordings

Constructed collaboration with other initiatives

• PhRMA : co-hosted “Biosimilar” workshop
• AHWP : co-hosted “Combination Product” workshop
• TATF/USAID : co-hosting “Supply Chain” workshop
AHC Training Activities in 2012

2012 Biosimilar Workshop
- **Date:** April 3~5, 2012
- **Title:** AHC Biosimilar Workshop
- **Participation:** About 430 Attendees including 30 speakers and 8 delegates

2012 AHC/RHSC Awareness Workshop
- **Date:** August 21, 2012
- **Title:** AHC/RHSC Awareness Workshop
- **Participation:** About 100 in attendance including 18 speakers and 9 delegates

2012 Pharmacovigilance Workshop
- **Date:** October 25-26, 2012
- **Title:** Pharmacovigilance Workshop
- **Participation:** About 210 Attendees including 13 speakers

2012 Medical Device on Combination Products Workshop
- **Date:** November 4, 2012
- **Title:** APEC-AHC-AHWP Joint Workshop on Medical Device Combination Products
- **Participation:** 400 in attendance including speakers and delegates from 25 conomies
Biosimilars Workshop

Venue: Grand Hilton Seoul Hotel, Seoul, Korea
Date: April 3rd – 5th, 2012

Participants:
- 30 Experts Invited as Chairs, Speakers and Panels
  - Regulators representing 7 economies
- 8 Delegates Invited from APEC Travel-Eligible Economies
- 50 International Participants & 350 Domestic Participants

Follow up of 2009 AHC Biosimilars Workshop held in Seoul, Korea
Performed on the basis of the Biosimilars Roadmap developed by KFDA
Biosimilars Workshop

**OUTCOME**

**Discussions**

**Stepwise Approach**
- Due to the insufficient experience on the biosimilars development, stepwise approach are necessary with regulators

**Flexible Assessment**
- Comprehensive information is needed to prove the similarity of reference drug
- Regulators need to have the flexibility when assessing similarity with the reference drug

**Regulatory Harmonization**
- Regulatory harmonization on the reference product, clinical trial and the scope of biosimilars is required

**Regulator’s Meeting**

**Harmonization of terminology and definitions** within the biosimilar lexicon and regulatory language would be essential as it provides a basis for communication at the same level

**Regulators should not lose sight** of the overall purpose of the development of biosimilars, which is the availability of affordable alternatives to biologics drugs
Without regulatory harmonization this goal will not be achieved

**Harmonization** of the reference product would enhance global development of biosimilars, which should ultimately help in the cost reductions needed
Biosimilars Workshop

OUTCOME

Workshop Report

Containing Summaries of Discussions, Ideas and Recommendations

Has been drafted and to be endorsed by RHSC of APEC LSIF

Manufacturing Site Visit

Outcomes presented at the WHO Implementation Workshop
AHC/RHSC Awareness Workshop

**VENUE**
Grand Copthorne Waterfront Singapore

**DATE**
August 21, 2012

- **Participants:**
  - 31 Regulators from national regulatory agencies
  - 13 Experts from industry
  - 9 Delegates Invited from APEC Travel-Eligible Economies
  - 100 Participants
AHC/RHSC Awareness Workshop

**OUTCOME**

✅ **Key Topics**
- The formation of Industry Coalition (4 Sectors)
  - Medical device, Pharmaceuticals, Biotechnical products, Generics
- Broadening engagement - potential partnership with World bank, WHO
- Involvement of more APEC economies – Papua New Guinea, Chile

✅ **Concept note and Roadmap Presentation**

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<th>Topic</th>
<th>Leading Authority</th>
<th>Current status</th>
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<td>Pharmacovigilance</td>
<td>KFDA</td>
<td>Roadmap</td>
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<tr>
<td>Biotechnology Product</td>
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<td>GMP &amp; Supply Chain</td>
<td>US FDA</td>
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<td>Combination Product</td>
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<td>GCP Inspection</td>
<td>Thai FDA</td>
<td>Roadmap</td>
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<tr>
<td>MRCT</td>
<td>MHLW/PMDA(Japan)</td>
<td>Roadmap (endorsed)</td>
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Pharmacovigilance Workshop

VENUE
Novotel Ambassador Hotel, Seoul, Korea

DATE
October 25~26, 2012

OVERVIEW

✓ Participants:
  • 13 Experts Invited as Chairs, Speakers and Panels
  • 4 Regulators (Korea, USA, Singapore, China),
  • 210 Participants

✓ Performed on the basis of the Pharmacovigilance Roadmap being developed by KFDA

✓ Held as a regional workshop this year, which will be developed into an international workshop next year
Pharmacovigilance Workshop

Topics & Outcomes

Discussions

Global Status of Pharmacovigilance

- New PV legislation is effective since July 2012 in EU - PV SMF, consumer reports, non-serious post authorization reports within 90 days, benefit-risk ratio assessment etc.

Regulatory Systems in APEC Economies

- China - Regulations for ADR monitoring (1999), 1 National and 34 provincial monitoring centers
- Singapore - Maximising IT tools and electronic health record for signal detection and data mining
- USA - Establish an active surveillance system, Sentinel Initiative to evaluate possible medical product safety issues quickly.
- Korea - Reexamination, reevaluation, voluntary ADR reporting, Drug Utilization Review System

Issues and Challenges of Regulatory Harmonization in PV

- Concept changes from Drug safety to Patient safety
- Investment to company-wide PV system in industry vs transparent decision-making in regulatory authority
- General confidence and trust over the word
## Pharmacovigilance Workshop

### Results

<table>
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<th>The importance of Pharmacovigilance through drug life cycle</th>
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<tr>
<td>The lack of integrated regulations and guidelines in the APEC region</td>
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<tr>
<td>Collaboration to develop pragmatic PV standards</td>
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</table>

### Regulators’ Meeting

- The need for sharing information
- Minimize gap between national regulatory systems

### PV Center On-Site Visit

- Korea Institute of Drug Safety & Risk Management (KIDS)
- Regional PV Center (Seoul National University Hospital)
Participants:
- 400 International Participants including 22 delegates,
  Experts from 25 travel-eligible economies

Performed on the basis of the Combination Products Concept Note developed by Chinese Taipei FDA
Medical Device Combination Products Workshop

Outcomes

Discussions

Guiding Principles for Regulation of Combination Products

- Understanding primary mode of action and Use of historical jurisdictional decisions
- Prompt assignment to appropriate review team according to types of products
- Timely and effective premarket review process and Consistent postmarket system
- Predictable and transparent regulatory process

Regulatory Convergence

- Harmonized and concise definition for a combination product
- Mechanism for designation of primary mode of action in review process
- Consistent application of GMP and quality system requirements
- Adverse event reporting system based on type of marketing application
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II. Planning of 2013 Projects
AHC 2013 Workshop Plan

• Four International Workshops

- Supply Chain Integrity
- Pharmaco-Vigilance (?) (tbc)
- MRCT
- ?
Supply Chain Integrity Workshop

**Schedule**

**DATE** May 22~23, 2013

**VENUE** Seoul, Korea

**TOPICS**

- Falsified/counterfeit medicines public awareness
- Establishment of an APEC “Single Point of Contacts (SPOCs)” System

**Hold the Date Announcement**

**Co-hosted By**

- APEC TATF
- APEC (LSIF/RHSC)
- USAID/ FDA
Thank You for Your Attention!

Send your additional comments or questions to parkkl@korea.kr

Please visit our website at www.apec-ahc.org