



**Asia-Pacific  
Economic Cooperation**

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**2016/SOM1/CTI/054**

Agenda Item: 11

## **LSIF Convenor's Summary Report to CTI**

Purpose: Consideration  
Submitted by: LSIF PG Chair



**First Committee on Trade and Investment Meeting  
Lima, Peru  
28-29 February 2016**

## **OAA ISSUE AREA:**

### **CONVENOR'S SUMMARY REPORT TO CTI**

#### **LIFE SCIENCES INNOVATION FORUM**

Established by Leaders' mandate in 2002, the LSIF continues to implement its 2004 Strategic Plan, which calls on the LSIF to shape policies that will contribute to the development of the medical life sciences sector and ultimately the improvement of public health in the APEC region. To achieve this goal, the LSIF has focused on three areas: research and development; regulatory harmonization; and health policy and innovation.

The LSIF RHSC is one of the LSIF's leading initiatives. The steering committee has been supported by the APEC Harmonization Center in Seoul, Korea. Since 2011, the RHSC has been working on implementing a strategic roadmap to achieve regulatory convergence for medical products by 2020. Roadmaps have been developed to advance convergence in ten priority work areas, including biotherapeutics; multi-regional clinical trials (MRCT); global medical product quality and supply chain integrity; good clinical practice (GCP) inspection and good review practices (GRP). There are multi-sectoral working groups leading the development and implementation of the roadmaps for each priority work area. There is now a focus on establishing a network of Centers of Excellence to move towards implementation of the road maps.

The LSIF held a suite of meetings during SOM1 in Lima, Peru: the LSIF RHSC Global Medical Product Quality and Supply Chain Integrity Workshop (20-24 Feb); LSIF Regulatory Harmonization Steering Committee (22-25 Feb); LSIF Planning Group (26 Feb); and LSIF-Health Working Group Joint Session (28 Feb).

#### **1. PROPOSED WORK PLAN FOR 2016 IN RESPONSE TO 2016 APEC PRIORITIES, WITH PARTICULAR REFERENCE TO APEC LEADERS/ MINISTERS/SOM DECISIONS OF 2015:**

##### **A) SUPPORT THE MULTILATERAL TRADING SYSTEM**

##### **B) ADVANCING REGIONAL ECONOMIC INTEGRATION**

- Achieving the Bogor Goals
- Exploring an FTAAP
- Global Value Chain Cooperation
- MSMEs Internationalization
- Next Generation Trade and Investment Issues
- Environmental Goods and Services (EGS)/Green Growth
- Services
- Investment

##### **C) STRENGTHING COMPREHENSIVE CONNECTIVITY AND INFRASTRUCTURE DEVELOPMENT**

- Implementation of the Supply-Chain Connectivity Framework and Action Plan (SCFAP)
- New Initiative/Target for Supply Chain Connectivity/Trade Facilitation (Post-SCFAP)
- Contributions to the implementation of the APEC Connectivity Blueprint for 2015-2025; APEC Multi-year Plan on Infrastructure

**D) EXPANDING REGULATORY COOPERATION AND ADVANCING REGULATORY CONVERGENCE**

Endorse the activities of the Regulatory Harmonization Steering Committee.

Welcome the progress to establish an APEC Regulatory Sciences Center of Excellence (CoEs) as a new and sustainable model for advancing regulatory convergence on a global scale. Endorse the RHSC's new operating model for COEs.

Welcome the proposed two CoE training sessions for multi-regional clinical trials - one in Singapore and one in Beijing to promote global drug development as well as a training curriculum on good clinical practices. Note that a CoE for bio-therapeutics is next in line.

Thank the APEC Harmonization Center and the Government of Korea for its continued commitment to the LSIF's regulatory harmonization agenda. Look forward to the AHC-supported CoE core competency programs in 2016.

Welcome the extensive work done through the Global Medical Supply Chain Integrity Workshop earlier this week on the areas of good manufacturing practices, product traceability and authentication, detection technologies, internet sales, and good import/export practices. We look forward to receiving the Roadmap for Medical Product Quality and Supply Chain Integrity for consideration at SOM3. We also look forward to receiving the final toolkits by SOM1 2017.

- Standards and Conformance
- Good Regulatory Practice
- Food Safety
- Cooperation with the Economic Committee, Services and Regulatory Reform
- New Regulatory Issues, etc.

**E) PROMOTING INNOVATIVE DEVELOPMENT, ECONOMIC REFORM, QUALITY GROWTH; CONTRIBUTIONS TO OTHER CROSS-CUTTING INITIATIVES**

Support the development of an agenda for the cross fora dialogue with the Health Working Group (HWG) and Senior Finance Officials (SFOM) and other relevant groups to examine the fiscal and economic implications of early retirement due to ill health. The target date for the dialogue is mid-October 2016, alongside the APEC Finance Ministers Meeting.

Welcome the LSIF's robust partnership with the Health Working Group (HWG) and look forward to contributing to Peru's APEC 2016 health priorities including through the 6th APEC High-Level Meeting on the Health & the Economy during SOM3 in August.

Note that HLM6 can inform the cross-for a dialogue in October. Consider an innovation theme.

Welcome forthcoming activities of the APEC Health Sciences Academy at Peking University in Beijing, China, including the holding of a MRCT workshop in mid-year.

Welcome and note the progress of the APEC Mental Health Digital Hub and encourage APEC economies' support for launching this hub. Note the upcoming collaboration with the WHO and World Bank to hold a high level event in the margins of the spring meetings (April 13-15) to "bring mental health out of the shadows".

Endorse the holding of the APEC HPV / Cervical Cancer Workshop on during SOM3 in Lima in August 2016.

Welcome work this year to implement the APEC-GHSA Framework on Infection Prevention and Control (IPC) and the development of additional IPC support packages.

Welcome the continued implementation of the APEC Blood Supply Chain 2020 Roadmap through the APEC Blood Supply Chain Partnership Training Network's activities in Lima, Peru in 23-24 June and in Southeast Asia later this year.

Welcome the continued of the APEC Business Ethics Initiative for Pharmaceuticals and Medical Devices in the SMEWG.

- Digital Economy

Endorse the LSIF moving forward with the E-Commerce Steering Group to form a virtual working group to develop solutions for the use of big data analytics in medical research. Note that volunteers for the Virtual Working Group are to inform the LSIF Program Director by March 31.

- IPR

Welcome the progress made by APEC LSIF Biomedical Technology Commercialization Center (TCTC). Welcome and look forward to the upcoming regional workshops.

Congratulate Korea and Thailand on their continued efforts to promote networking among researchers in the region and experts in the biomedical sector to help establish an infrastructure and stimulate innovation and commercialization in the APEC region.

Note the importance of the 2008 LSIF Enablers of Investment Checklist as an important tool for promoting innovation in life sciences. Having members grade their own policies across government against the standards of measurement in the checklist and against one another helps them determine where they may be meeting a high standard and where they could improve their ability to attract investment in the healthcare sector. Invite APEC Economies interested in completing the checklist in 2016 to notify the Program Director by end of March.

- Food Security,
- Human Capital Development

### **3. ACTIVITIES WITH ABAC (INCLUDING RESPONSES TO ABAC'S 2015 RECOMMENDATIONS) AND/OR OTHER EXTERNAL STAKEHOLDERS**

Welcome the progress of the ABAC - LSIF/RHSC pilot projects testing the efficiency of the use of a common data standard for product verification in the pharmaceutical supply chain and look forward to reports on progress of the pilot projects in Malaysia and the Philippines.

#### **4. EXPECTED OUTCOMES/DELIVERABLES FOR 2016**

Workplan and possible set of principles for assessing and addressing (i) the fiscal and economic impact of ill health, and (ii) the broad economic impact of health as an outcome of the October 2016 cross fora dialogue with the Health Working Group (HWG) and Senior Finance Officials (SFOM) and other relevant groups.

Statement of the 6<sup>th</sup> APEC High-Level Meeting on Health & the Economy

A cross-fora framework (with ECSG and HWG) guiding the future Use of Big Data in Medical Research, with goal of developing an eventual library of Use-Based Models

APEC HPV and Cervical Cancer Roadmap to implement 2014 policy forum recommendations

Launch of the APEC Mental Health Digital Hub

APEC Peking University Pilot Program for Multi-Regional Clinical Trials (MRCT) and Good Clinical Practices (GCP) Inspection

LSIF/RHSC Global Medical Product Quality and Supply Chain Integrity Roadmap and Associated Toolkits

The RHSC's new operating model for Regulatory Sciences Centers of Excellence

Reports from the ABAC - LSIF/RHSC pilot projects in Malaysia and the Philippines testing the efficiency of the use of a common data standard for product verification in the pharmaceutical supply chain

#### **5. DECISION POINTS NEEDED FROM CTI**

Endorse the LSIF Convenor's report and recommendations therein.