



**Asia-Pacific
Economic Cooperation**

2014/SOM3/CTI/051
Agenda Item: 10

Life Sciences Innovation Forum Convenor's Summary Report to CTI

Purpose: Consideration
Submitted by: LSIF Chair



**Third Committee on Trade and Investment
Meeting
Beijing, China
16-17 August 2014**

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 services and innovation. The LSIF currently has two subcommittees: the Regulatory Harmonization Steering Committee (RHSC) and the Research and Development Steering Committee (RDSC). At SOM3, the LSIF welcomed the establishment of a third steering committee on health innovation policy to better manage and prioritize the emerging health innovation work of the LSIF, including in cooperation with the HWG. Comments are requested on the draft Terms of Reference of the group by September 15.

The LSIF RHSC is one of the LSIF's leading initiatives. The steering committee is chaired by Health Canada and 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 8 work areas, including biotherapeutics; multi-regional clinical trials; global medical product quality and supply chain integrity; good clinical practice inspection and good review practices. There are multisectoral working groups leading the development and implementation of the roadmaps for each priority work area.

The LSIF met in Special Session at SOM3 on August 14, 2014. This LSIF's Regulatory Harmonization Steering Committee (LSIF RHSC) met concurrently from August 14 – 16, 2014. The LSIF also met with the Health Working Group (HWG) in joint session on August 13. The LSIF co-hosted the 4th APEC High-Level Meeting on Health & the Economy on August 15 together with the Health Working Group.

- 1. PROPOSED WORK PLAN FOR 2014 IN RESPONSE TO 2014 APEC PRIORITIES, WITH PARTICULAR REFERENCE TO APEC LEADERS/ MINISTERS/SOM DECISIONS OF 2013:**
 - A) SUPPORT THE MULTILATERAL TRADING SYSTEM**
 - B) ATTAINING THE BOGOR GOALS, TRADE AND INVESTMENT LIBERALISATION, REGIONAL ECONOMIC INTEGRATION**
 - Achieving the Bogor Goals

Received updates on the LSIF RHSC's progress implementing the strategic roadmap to achieve regulatory convergence for medical products by 2020. Work is underway in ten priority work areas, including biotherapeutics; multi-regional clinical trials; global medical product quality and supply chain integrity; and good review practices

The LSIF welcomed progress on the RHSC's efforts to establish a Center of Excellence for Regulatory Sciences in Multi-Regional Clinical Trials, work on Good Review Practices, as well as work on implementing the Roadmap on Supply Chain Integrity through targeted efforts to address internet pharmacies and supporting a common approach to data standards for track and trace in the supply chain.

- Exploring an FTAAP
- Global Value Chain Cooperation

ABAC presented a proposal to collaborate with the LSIF RHSC on a global data standards pilot project for medical products. Where economies seek to adopt standards for product verification and serialization along the supply chain they should be consistent with international guidance. A common approach to the adoption of global data standards will reduce costs for both government and industry

in addition to assuring the integrity of the supply chain. The LSIF endorsed work with the CTI and the ABAC to take forward work on Global Data Standards.

The LSIF agreed to explore work in 2015 on identifying impediments in the medical products supply chain.

- Next Generation Trade and Investment Issues
- Services
- Investment
- Environmental Goods and Services (EGS)

C) STRENGTHENING COMPREHENSIVE CONNECTIVITY AND INFRASTRUCTURE

- Implementation of the Supply-Chain Connectivity Framework and Action Plan;
- Contributions to the Implementation of the APEC Framework on Connectivity; APEC Multi-year Plan on Infrastructure Development and Investment; and APEC Travel Facilitation Initiative

C) EXPANDING REGULATORY COOPERATION AND ADVANCING REGULATORY CONVERGENCE

The LSIF welcomed the progress made on regulatory convergence, including progress with the establishment of a Regulatory Sciences Center of Excellence to build regulatory capacity for the evaluation of clinical trial results.

The LSIF endorse efforts to promote public awareness and research on illegal internet pharmacies

D) CONTRIBUTIONS TO INNOVATIVE DEVELOPMENT, ECONOMIC REFORM AND GROWTH, IN PARTICULAR, APEC'S LEADERS' GROWTH STRATEGY

- Digital Economy
- IPR

The LSIF Research Committee also has made significant progress with the establishment of a biomedical commercialization training center. Led by Korea, Thailand, and the Association of University Technology Managers as the preferred trainer, the Committee is securing resources to launch the training center later this year. Again, this will be a first for APEC and globally. It will jump start the ability of economies to bring their biomedical innovations to market and reap the rewards of their own IP. We will keep the CTI informed of progress. The commitments made to date in terms of resources are significant.

The LSIF endorsed efforts to promote public awareness and research on illegal internet pharmacies

E) OTHER AREAS, INCLUDING APEC-WIDE INITIATIVES ON HUMAN SECURITY, FOOD SECURITY, APEC REFORM, GENDER AND STREAMLINING

The LSIF endorsed work in cooperation with the Health Working Group (HWG) to address non-communicable disease and mental health, including a collaborative road map for innovative ways of addressing the economic and social burden of mental health

The LSIF endorsed the publication of the LSIF-ABAC Study on Workforce Productivity.

Endorsed implementation of a project on improving the safety of blood supply chain and endorsed continued work in cooperation with the HWG to address healthcare-associated infections and anti-microbial resistance.

The LSIF Planning Group supported plans to continue joint work with the Health Working Group (HWG) on the APEC High-Level Meeting on Health & the Economy and endorsed the Healthy Asia Pacific 2020 initiative.

2. ACTIVITIES UNDERTAKEN WITH ABAC (INCLUDING RESPONSES TO ABAC'S 2013 RECOMMENDATIONS) AND/OR OTHER EXTERNAL STAKEHOLDERS

Joint Pilot Project between ABAC and LSIF RHSC on global data standards for medical products.

The LSIF Planning Group endorsed undertaking a joint project with the ABAC on workforce productivity.

3. FORECAST OF OUTCOMES/DELIVERABLES FOR 2014

Launch the APEC Bio-medical Technology Commercialization Center hosted jointly by Korea and Thailand.

Publication of the LSIF-ABAC Study on Workforce Productivity.

Road map for innovative ways of addressing the economic and social burden of mental health

4. DECISION POINTS NEEDED FROM CTI

Welcome and support the work of the LSIF Regulatory Harmonization Steering Committee

Recognize the LSIF contribution to the High Level Meeting on Health and the Economy, which approved a Healthy APEC 2020 framework that includes many of the LSIF projects.

Welcome the progress made on the establishment of the regulatory sciences Center of Excellence and the upcoming establishment in December of the Bio-Medical Commercialization Training Center

Note that revised LSIF TORs and Health and Innovation Committee TORs will be submitted to CTI for approval at SOM1, 2015

Support work going forward on identifying impediments in global value chains; the integrity of the medical products supply chain; cross-fora collaboration and public private partnerships to address health challenges impeding women's access to the economy; issues such as anti-microbial resistance, and, the economic and social burden of mental disorders. A workshop to develop a road map for innovative approaches to mental health will be held here in Beijing on August 20-21.