Final Report of the LSIF Planning Group Meeting
30 January 2013
Jakarta, Indonesia

Presentations and meeting papers from this meeting can be accessed through the APEC Meeting Document Database at http://mddb.apec.org/. In this report, meeting papers are listed by their Document Number under the relevant agenda item.

- See *LSIF PG Document Classification List* (2013/SOM1/LSIF/000)
- See *LSIF PG Meeting Agenda* (2013/SOM1/LSIF/001)

1. Welcome and Introductions

2. Expectations for the Meeting

The LSIF Planning Group convened in Jakarta on 30 January 2013. The small group meeting was chaired by Ms. Barbara NORTON and attended by representatives from the following APEC member economies: China, Indonesia, Korea, Philippines, Chinese Taipei, Thailand, and the United States.

3. APEC 2013

- See *APEC 2013: Sustainable Growth with Equity – Health* (2013/SOM1/LSIF/002)

Ambassador Yuri Thamrin, APEC SOM Chair, opened the meeting and congratulated the LSIF on its achievements in 2012. He said he expects the LSIF to make many more achievements this year and in the future. The SOM Chair presented the APEC 2013 theme: "Resilient Asia Pacific, Engine of Global Growth." Indonesia's goal for APEC this year is to make the region a model for the world in terms of sustained growth. The SOM Chair provided an overview of Indonesia's APEC priorities: 1) Attaining Bogor Goals; 2) Sustainable Growth with equity; and, 3) Promoting connectivity.

The sub-themes for Priority 1: Attaining Bogor Goals, include: a) support for multilateral trading system (including working leading up to hosting the December Ministerial); b) regional economic integration, including plans to strengthen development cooperation; and c) strengthening regional cooperation, including regulatory cooperation and structural reform.

The sub-themes for Priority 2: Sustainable Growth with equity, include: a) SME competitiveness; b) financial inclusion; c) health; and, d) food security. Under Health, Indonesia would like to examine health's role in driving sustainable growth, with a focus on health financing and the health workforce. The goal is to develop a model of a sustainable health system. The hope is

that the LSIF will contribute significantly to this model at the same time as LSIF continues its work program.

The sub-themes for Priority 3: Promoting Connectivity, include: a) infrastructure development; b) institutional cooperation; and c) people to people connectivity. Indonesia also attaches importance to mainstreaming ocean issues.

Chair LSIF PG responded that she hopes that the LSIF will live up to Indonesia's expectations. She observed that the LSIF has received international recognition for its work on health innovation. The LSIF is also working closely with other international organizations, including the World Health Organization (WHO) and is drawing on relevant work conducted in other forums such as the World Economic Forum (WEF). She noted that Dr. John Beard of the WHO currently serves on the LSIF Board. The LSIF's work on wellness and prevention was also recognized at the 2013 WEF Davos meeting. The Economist magazine has also taken up the issue of healthcare financing this year. The Chair LSIF PG noted that she had been invited to present to outside organizations on the LSIF's work.

The Chair of the Committee on Trade and Investment (CTI), Mr. John LARKIN, discussed the CTI's 4 main priorities for 2013: 1) support for multilateral trading system; 2) regional economic integration/trade and economic liberalization (attaining Bogor goals); 3) promoting connectivity; and, 4) contributions to the APEC Growth Strategy and Cross-Cutting mandate. He observed that APEC has had a major role in driving the work of the WTO, especially through its work on the Information Technology Agreement (ITA), trade facilitation, and on environmental goods and services (EGS). Indonesia is hosting the 9th WTO Ministerial Meeting in Bali in December 2013. The Chair CTI observed that APEC could support the WTO this year through continued work on the Bogor Goals and work streams such as the investment facilitation action plan and the single window system. The LSIF's work on regulatory cooperation and convergence should also be recognized as part of this effort.

The Chair CTI discussed the importance of APEC's "cross-cutting mandate". He noted that there has been a dramatic increase in initiatives launched by Ministers and Leaders that cut across work of many groups – e.g. travel facilitation, cross border education cooperation, infrastructure development, and investment. He noted that the LSIF and the Health Working Group (HWG) are among the groups working together and welcomed views on how the joint work is going. He observed that there are many synergies in the work of both the CTI and Economic Committee (EC) and noted the importance of close collaboration with the APEC Business Advisory Council (ABAC).

The Chair LSIF PG thanked the Chair CTI. She added that the LSIF also collaborated with the SMEWG on the initiative in support of ethical business practices in the pharmaceutical and medical device sectors. She further noted that the LSIF PG is trying to reinvigorate the scientific aspect of the LSIF's work through the LSIF Research Committee.

4. Review of 2012 LSIF Accomplishments

The Chair LSIF PG reviewed the list of the LSIF's 2012 accomplishments as well as the tentative calendar for the year.

In 2012, APEC Economic Leaders…

- Recognized that a healthy population is crucial for sustainable economic development and innovative growth in the APEC region;
- Encouraged further steps to strengthen health systems by preventing non-communicable diseases, promoting and investing in health and healthy lifestyles and wellness across the life course starting from maternal, infant and child health through to the end of life;
- Agreed to continue work in the APEC Life Sciences Innovation Forum to enhance cooperation among government, scientists, and business to promote innovation and address issues that impact specific innovative technologies;
- Recognized the important role of business and public-private partnerships in promoting the elaboration of codes of conduct in the private sector and measures to fight corruption, especially measures that support the promotion of ethical business practices in interactions between government, business and other stakeholders.

In 2012, APEC Ministers…

- Recognized that investments in health at all stages of life from pre-natal through aging are investments in the future;
- Welcomed work to prevent and reduce the burden of non-communicable diseases and promote health and healthy lifestyles;
- Pledged their support to improve health, especially maternal and child health, as a source of dynamic growth;
- Welcomed work to address the economic and public health burden of healthcare associated infections (HAIs) and encouraged officials to work with stakeholders to reduce the incidence of infections in healthcare settings;
- Welcomed the development and implementation of a roadmap to ensure the quality and integrity of the medical products supply chains and availability of safe and effective medical products to our citizens;
- Welcomed progress in the implementation of APEC principles for voluntary codes of business ethics and look forward to further APEC efforts to strengthen ethical business practices through capacity building activities.

5. LSIF Enablers of Investment Checklist

- See *LSIF Enablers of Investment Checklist* (2013/SOM1/LSIF/003)

The Chair LSIF PG observed that for the past few years the LSIF Enablers of Investment Checklist has served as an effective tool for helping governments identify the policies needed to support

the development of an innovative life sciences sector. The Checklist consists of a set of overarching principles that include policies on issues confronted by industry. In completing the checklist, governments reported learning more about the ministries and other stakeholders inside and outside of government responsible for carrying out various policies.

Chinese Taipei commented that the Checklist helped foster greater cross-ministry cooperation. The process of completing the Checklist also helped Chinese Taipei determine how to improve its biotechnology environment. Chinese Taipei now does a self-check almost every year and offered to assist other APEC Member economies with filling out the Checklist.

The Chair LSIF PG encouraged economies that have not yet completed the Checklist to do so this year. She invited China, in particular, to consider completing the Checklist since it will host APEC next year. Once there is a critical mass, it would be useful for the LSIF Secretariat to undertake an analysis of the Checklists, summarizing where the region stands as a whole and comparing APEC Economies' progress on select enablers. At the LSIF meeting in St. Petersburg, Russia in June 2012, economies discussed establishing a mentorship program where economies could help others by providing guidance. The Chair LSIF PG thanked Chinese Taipei for offering to serve as a mentor. The Chair also proposed hiring a consultant that could help economies complete the Checklist.

Indonesia added that it is currently working on making changes to its policy environment based on what it learned from completing the Checklist last year. Indonesia noted that it used the tool to assess areas for improvement and that inter-sectoral collaboration with science and technology and the private sector is already underway

Chinese Taipei and Thailand supported seeking APEC funding for a consultant to guide developing economies through the process of completing the Enablers of Investment Checklist. Thailand and China both said they will consider completing the Checklist.

ACTION: By the 3rd APEC Project Funding Round, the LSIF Secretariat should develop a Concept Note for funding a consultant to help developing economies fill out the Enablers of Investment Checklist. The Round 2 Concept Note submission deadline is May 31, 2013; the Round 3 Concept Note submission deadline is September, 18, 2013.

6a. Principles for Life Sciences Sector Development

- See *LSIF Enablers of Investment Checklist* (2013/SOM1/LSIF/003)

Chair LSIF PG said the Indonesia Ministry of Trade Senior Official mentioned to the LSIF Co-Chairs that a set of principles for developing the life sciences sector would be a great "quick win" for the LSIF at the Meeting of Ministers Responsible for Trade (MRT) April 20-21 in Surabaya. The Principles would draw on the Enablers of Investment Checklist and other relevant already agreed APEC documents, including innovation principles, the NCD Action Plan and principles for

ethical business practices. The 2012 Leaders Statement also emphasized promoting an innovation friendly environment and promoting the successful adoption of innovation. Leaders gave the task to subfora to address issues that affect technologies.

ACTIONS:

1. ***LSIF Secretariat to organize a small drafting group to pull together the best practice principles.***
2. ***Volunteers for the drafting group to inform the LSIF Planning Group Chair or the Program Director of their interest.***
3. ***First draft for review by March 6.***
4. ***Among other things draw on the enablers of investment checklist, the already agreed APEC innovation principles, the NCD action plan, ethical business practices, and other relevant APEC documents***

6b. View from Industry on the Principles for Life Sciences Sector Development

- See *Policy Principles to Promote Biotechnology* (2013/SOM1/LSIF/004)

Ms. Lila Feisee, Vice President of International Affairs at the Biotechnology Industry Organization (BIO), presented the biotechnology industry's views on the legal and regulatory framework needed to grow the biotech sector.

Ms. Feisee explained that only one out of 10 biopharmaceutical discoveries is successfully developed and commercialized. Many fail after a concept is proven and before regulatory approval is obtained. This process alone costs more than $1.2 billion and takes more than ten years. The private sector funds 96 percent of the biotechnology R&D. Investors fund capital-intensive biotech innovation only if they are confident that, if a product beats the odds and makes it to the market, they will realize a positive return on their investment.

Ms. Feisee outlined the four pillars of policy principles that would ensure a robust biotechnology sector: (1) research collaboration; (2) intellectual property; (3) science-based and transparent regulatory approval procedures; and, (4) market access.

Research collaboration is essential for ensuring a robust biotechnology sector. Support for early research through grants, funding, universities, and research institutions, is critical. Research then needs to be brought to the marketplace through a strong legal framework for transferring research from public institutions to companies. Companies are then able to generate investment funding to further develop the product. It is important to allow the transferor (licensor) flexibility to find the appropriate partner for commercialization. A dozen economies are currently in the process of implementing technology transfer laws

The second pillar is Intellectual Property. Because biotechnology is a research and capital intensive industry, economies need an instrument that allows an investor to get a return. IP is

protected through patent terms and data exclusivity. A patent term of 20 years from filing effective-term for most inventions is approximately 17 years due to patent processing delays. For biopharmaceuticals only 7 to 10 years – due to the additional time required to fully develop and obtain regulatory approval for the product (Some economies, such as Chinese Taipei, restore the patent terms for biotech products to offset time lost in the regulatory review process).

Data exclusivity laws provide protection for test data that regulatory authorities require for approval. Before a biopharmaceutical company can make a product available to patients, it must conduct extensive analytical, preclinical, and clinical research tests to prove to regulators that the product is safe and effective. These tests account for more than 90 percent of private sector research and development funding.

Thailand commented that it agreed with the views expressed in Ms. Feisee's presentation, but noted that concerns might be raised on how the poor can obtain access to biotechnology innovations. It might be more accepted if economies could see how to diffuse these technologies to the poor. Ms. Feisee offered to share her industry's position on access to medicines in developing economies after the meeting. The document was subsequently circulated to the Planning Group by the Program Director.

The Philippines added that it has made major advances in biotechnology, however, it has experienced many challenges reforming its health sector. The economy now has a more vibrant regulatory framework. Philippines suggested that a public-private partnership to assist the poor with access to new technologies.

The Philippines also noted that the economy does not provide for Patent Term Extensions, but is trying to explore other ways to facilitate the granting of patents in the field of biotech. The Philippines recognizes the importance of the biotechnology field. It has been a member of the Patent Cooperation Treaty for almost 12 years. The Philippines launched on 29 January a prosecution agreement pilot with the U.S. Patent and Trademark Office and maintains a prosecution agreement with Japan. The economy has been coordinating with the pharmaceutical sector and greatly appreciates the amount of investment that is poured into the development of new molecules. The Philippines is also in the process of upgrading the competencies of new patent examiners. Ms. Feisee offered to coordinate with the Philippines on these matters.

Korea explained that its legal framework was designed to foster biotechnology development and that biosimilars regulation is essential.

Ms. Feisee explained that as more APEC economies get into the biosimilars space, it is important that they have good regulations across the board for both originator products and biosimilars. Korea is spearheading the biotherapeutic roadmap in the LSIF RHSC.

Indonesia asked if there is an incentive policy for preventive medicine, such as tools for genetic screening. Ms. Feisee responded that in the United States there is a great deal of funding that

goes into basic research, including genomics, which goes through the National Institutes of Health. The research covers a number of areas, not just one. Research is continued at universities. The private sector then works with universities to commercialize promising research. The policy incentives are thus the early stage funding and the good framework for moving the research forward.

China observed that the Chinese biotechnology industry is developing very quickly. The Chinese Government is paying more attention as a result. Last year the Government issues its first 5-year plan on biotech and is planning to invest more money into R&D.

ACTION: BIO to send policy principles on access to medicines to PD for circulation to the LSIF Planning Group.

7. LSIF Research Committee and Collaboration with CSA

- See *LSIF Research Committee Co-Chair Nominees* (2013/SOM1/LSIF/008)

Chair LSIF PG observed that the LSIF is working on reinvigorating its work on R&D and commercialization of research. Last year the LSIF Board approved the appointment of two additional Co-Chairs to the LSIF Research Committee, Dr. Chung-Liang Chien of Chinese Taipei and Mr. Mark Crowell of the United States.

Dr. Chung-Liang Chien was present at the meeting and said that it was an honor to serve in the co-chair position. Dr. Chung-Liang is the Deputy Executive Secretary in the Office of Science and Technology in the Executive Yuan. He also is a Professor in the Dept. of Anatomy and Cell Biology in the College of Medicine at National Taiwan University.

Mr. Mark Crowell who heads the office of commercialization at the University of Virginia is skilled in the commercialization of research. Mr. Crowell brings with him expertise on how promising research in the health sector can be commercialized. The Research Committee's excellent foundational work on developing the Asia Pacific Cohort Consortium with its many institutions has been instrumental in bringing institutions together to exchange information and begin collaborations. Such collaborations result in the development of potentially promising research and technologies. APEC economies would benefit greatly from his expertise as they look to leverage their research into economic benefit.

The LSIF PG approved the LSIF Board's decision to have Dr. Chien and Mark Crowell join as Co-Chairs of the Research Committee. The Chair LSIF PG suggested that the LSIF Research Committee should consider collaborating with the new APEC Chief Science Advisors (CSAs), who will be meeting at SOM3 in Medan. Chinese Taipei agreed with the Chair's suggestion.

ACTIONS:

(1) Approved the LSIF Board's Decision to have Dr. Chien and Mark Crowell join as Co-Chairs of the LSIF Research Committee
(2) LSIF Research Co-Chairs to draft a note outlining their work priorities in 2013 by April. Note to include ideas for collaboration with the Chief Science Advisors Meeting
(3) Advisor to the Co-Chairs to meet with Chair CSA Meeting during SOM 1 and report back.
(4) LSIF Research Committee Meeting would be held with LSIF in Special Session at SOM 3

8 & 9. Communications and Public Affairs Unit / LSIF Website Proposal

- See *LSIF Satellite Website Proposal* (2013/SOM1/LSIF/005)
- See *APEC Secretariat Communications and Public Affairs Update* (2013/SOM1/LSIF/016)

The APEC Secretariat's Communications and Public Affairs Unit (CPAU) discussed some of the tools available to help get the message out on all the work that APEC is doing. One of the tools available is a satellite website for sub-fora. In that context, the Chair LSIF PG put forward a proposal to launch a satellite LSIF website to provide more detailed information on LSIF's work, text of speeches, meetings information, and links to meeting documents. The purpose of this is to have a larger ability to promote the work of the LSIF. The Chair LSIF PG observed that the website could help the LSIF gain greater recognition for its work. She suggested the content be drafted and managed by the LSIF Secretariat and reviewed by the Chair. The CU noted that launching a satellite website is a free service provided by the APEC Secretariat.

ACTIONS:

(1) LSIF Secretariat to consult with the CPAU about what can and what cannot be put on website
(2) Questions to be considered include content, who could post material on the website, copyright issues, whether documents had to have an APEC logo, whether author approval would be needed and under what circumstances, how Chair LSIF Planning Group reviews content before posting.

10. Joint Work with HWG on APEC High Level Meeting on Health and the Economy

- See *The Economist "Healthcare in Asia 2013" Program* (2013/SOM1/LSIF/006)
- See *High Level Meeting on Health and the Economy* (2013/SOM1/LSIF/019)

Professor Agus Purwadianto of the Ministry of Health of Indonesia discussed Indonesia's APEC 2013 Goal of "Achieving Sustainable Growth with Equity". The goal is to develop a model of a sustainable healthcare system. He advised that the 3rd High Level Meeting on Health and the

Economy (HLM) will take place 18-19 September in Bali, Indonesia, alongside the Finance Ministers and Finance Senior Officials' Meeting. The HLM will conclude with recommendations for Finance Ministers, as well as the AMM and AELM on how to build a sustainable healthcare system.

Health financing will be an important part of the HLM discussion. Health financing systems in APEC economies need to be further developed in order to guarantee access to necessary services while providing protection against financial risk. It is important that the Ministries involved in allocating resources understand the benefits of a well functioning health system. Prof. Purwadianto presented some of Indonesia's keywords for health financing reform: equity; effective and efficient; transparent and accountable; appropriate technology; transferring the advanced technology; empowerment of scientist/industry; promotion; preventive; curative; rehabilitative.

Prof. Purwadianto noted that HWG and LSIF will hold preparatory meetings for the HLM at both SOM2 in Surabaya, Indonesia and SOM3 in Medan, Indonesia. The Chair LSIF PG said that she was pleased that a date had been set for the HLM and pleased that Indonesia's Ministry of Health had already reached out to the Ministry of Finance. She observed that the joint work this year has a very good platform on which to build on.

ACTIONS:

1. ***(1) LSIF Secretariat will work with GOI and HWG on development of agenda and logistical aspects, including invitations and speakers.***
2. ***(2) Economies to share experiences and lessons learned on health care financing in advance of the Surabaya preparatory meeting, with submission to the Program Director by March 15, 2013***
3. ***(3) LSIF Secretariat to approach the Economist for invitations to the Minister of Finance and Minister of Health to the March 20-21 EIU conference on healthcare financing to be held in Kuala Lumpur, Malaysia (completed)***
4. ***(4) Joint meetings in Surabaya and Medan with HWG to finalize arrangements and agenda***

11. Implementation of the APEC Action Plan on Reducing the Economic Burden of Non-Communicable Diseases (NCDs)

- See *Charter for Health Living* (2013/SOM1/LSIF/015)

The Advisor to the LSIF Co-Chairs welcomed continued progress in implementing the APEC NCD Action Plan. She commented that two public-private partnership (PPP) project proposals are being prepared for presentation at SOM2 in Surabaya, Indonesia: one on mental health (Janssen), and one on diabetes (Sanofi). She asked that APEC Economies consider submitting PPP proposals. They should be submitted to the LSIF Secretariat.

The Chair LSIF PG also observed that the World Economic Forum had just released a *Charter for Healthy Living* during the WEF annual meetings in Davos. The Charter could be useful as APEC economies continue implementing the NCD Action Plan.

ACTIONS:

(1) Additional details on the two PPPs to be provided in presentations at the joint session of LSIF and the HWG in Surabaya
(2) Economies interested in forming PPPs in specific NCD areas to contact the Program Director
(3) Include elements of the Global Charter discussed at Davos in the NCD work program in the lead up to the High Level Meeting.

12. **Maternal and Child Health**

The joint LSIF-WHO Study "*Investing in Maternal and Child Health: An Analysis of Costs, Benefits, and Returns"* was completed in September 2012. HWG Chair Dr. Svetlana Axelrod will brief the LSIF on additional work in the MNCH space at the SOM2 LSIF PG Meeting. The LSIF will also discuss the World Congress on Developmental Origins of Health and Disease (DOHaD) at that time.

ACTIONS:

(1) Final version of the LSIF/WHO study on maternal child health to be circulated to the LSIF Planning Group
(2) Chair HWG to brief LSIF on follow up work at the joint meeting in Surabaya at SOM 2.

13. Building Capacity for Hospital Accreditation by Addressing Healthcare-Associated Infections (HAIs)

- See *Study Proposal: The Economic Costs Associated Due to Limited Collection of Surveillance Dates on Healthcare-Associated Infections in APEC Developing Economies* (2013/SOM1/LSIF/007)
- See *APEC HAI 2013 Work Plan* (2013/SOM1/LSIF/021)

Mr. Bill Bishop, representing the Advanced Medical Technology Association (AdvaMed), presented updates on the LSIF's work on Healthcare-Associated Infections (HAIs). The LSIF in collaboration with the HWG organized the APEC High-Level Workshop on Reducing the Economic Burden of HAIs in Manila, Philippines on 25-26 July, 2012. Over 150 representatives from 18 APEC Member Economies, the World Health Organization, the Asian Development Bank, the International Nosocomial Infection Control Consortium (INICC), and the Asia Pacific Society of Infection Control (APSIC) participated in the meeting. Participants discussed the

public health and economic burden of HAIs in the region, which is estimated to afflict 5-19 percent of hospitalized patients and are a significant drain on health systems and government budgets. Participants also shared examples of effective policies and programs for addressing HAIs at both the economy and healthcare institution levels, and identified ways in which governments, patients, the private sector, and academia could work together to improve HAI prevention and control within economies.

The meeting agreed on a set of three initial steps APEC Member Economies should undertake to begin reducing the huge economic burden of HAIs in their economies: (1) invest in infection prevention and control policies and programs; (2) enhance data collection and surveillance; and (3) encourage partnerships and collaborations to help tackle the HAI burden. The meeting concluded with a set of recommendations calling on APEC Ministers to recognize the economic and public health burden of HAIs and encouraging APEC Member Economies to commit to working with stakeholders to reduce the incidence of infections in healthcare settings by establishing surveillance systems, baseline measurements, and targeted reduction goals at the economy and local levels.

Mr. Bishop discussed the HAI work proposed for 2013. The first project is a literature review of HAI cost studies conducted in APEC economies. The project will be lead by Professor Nicholas Graves, Health Economist at the Queensland University of Technology in Queensland, Australia. The goal is to have the paper completed and ready for presentation at an LSIF Workshop/Policy Dialogue on HAIs at SOM3 in Medan, Indonesia. This project is being funded by the U.S. Agency for International Development (USAID)'s APEC Technical Assistance and Training Facility (TATF).

Mr. Bishop then discussed the proposal to hold a LSIF workshop/policy dialogue on building capacity for hospital accreditation by addressing HAIs during the SOM3 series of meetings. The goal of the meeting would be to discuss steps that healthcare institutions can take to reduce the economic burden of HAIs as they work towards accreditation. The meeting will also look at how governments can support public and private healthcare institutions with meeting their accreditation goals. The literature review would also be presented during this meeting. Mr. Bishop noted that Indonesia's Ministry of Health is currently supporting its public hospitals with achieving international hospital accreditation.

Thailand asked about the cost of HAIs. Mr. Bishop said that a lot of money that is allocated to treat infections could be put to better use. Quality needs to be improved at the front end of care. Mr. Bishop cited the United States as an example. If you get an infection in a hospital in the U.S., the hospital is responsible for paying the bill. He said measurement is essential for reducing HAIs. If hospitals start to measure against a baseline then hospitals could be rewarded by the governments.

ACTIONS:

1. ***Economies interested in participating in the research with case studies/data to inform the Program Director***
2. ***Term of Reference of the Study to be circulated to LSIF Planning Group***

(3) Proposed agenda for the policy dialogue on hospital accreditation to be circulated by March 8.

(4) LSIF representatives to participate in the hospital tour on January 31.

14. Traditional Medicines

- See *Traditional Medicines* (2013/SOM1/LSIF/020)

Dr. Siswanto of Indonesia's Ministry of Health presented on the development of medicinal plants and traditional medicine. He said that traditional medicine is a new LSIF work area for this year, which is in line with APEC 2013 Priority 2 "Achieving Sustainable Growth with Equity". The World Health Organization estimates that about 80% of the world still depends on traditional medicines.

Indonesia would like to organize a seminar and workshop to discuss building a policy framework for developing traditional medicines. Indonesia would also like to develop common guidelines related to the research and development of traditional medicines and medicinal plants. The end goal of this work is to integrate traditional medicines into the conventional healthcare system.

Thailand thanked Indonesia for bringing in such an important valuable work topic. Thailand noted that it has a lot of traditional medicines and believes there are quite a few topics to be discussed in this area. Thailand observed that traditional medicines are not clearly an innovation, as they have been used for centuries. It was raised whether or not traditional medicines might be a contradiction to the LSIF's goals.

Philippines commended Indonesia for the initiative. It also faces the challenge of integrating traditional medicine into the healthcare system. It established a traditional medicine institute.

China noted that it has a long history of using traditional medicine and that have a very important role in public health in China. In China, there are specific laws and regulations on these products. There is also an independent government agency, the State Administration of Traditional Chinese Medicine, although the Sino Food & Drug Administration (SFDA) also has a special department responsible for regulating traditional medicines.

China added that 30-40% of medicines used in China are traditional. China continues to work on definitions and issues with conventional medicine. In the WHO Western Pacific Region, there was a forum for the harmonization of traditional medicines established 10 years ago, which includes China, Japan, Vietnam, Singapore, and others. Traditional medicine harmonization has been a challenge compared to chemical medicine because it is connected with culture and philosophy. China suggested starting with a small and attainable step in this area.

Chinese Taipei added that it established a center for traditional medicines and welcomed partnership with Indonesia and other economies. Regulatory convergence is important.

United States thanked Indonesia for the excellent presentation and commented that what often makes traditional medicine traditional is its usage. Many chemical drugs have the same active ingredients as some of the traditional medicines.

Indonesia responded that it is not looking to harmonize regulations for traditional medicines, as they are too different from economy to economy. It rather sees the LSIF providing a corridor for discussion. Indonesia will consider a topic for discussion.

The Chair LSIF PG noted the significant interest in this work area from multiple economies and suggested that Indonesia spearhead a dialogue on this topic. Indonesia could organize a small working group of economies to brainstorm ideas.

ACTIONS:

(1) Indonesia to pull a group together to work on an agenda for a dialogue on Traditional Medicines in the margins of LSIF in Special Session in Medan.
(2) Draft agenda circulated to LSIF Planning Group by February 28 for review and comment

15. LSIF Leadership

Chair LSIF PG reported that Minister Suwit Khunkitti of Thailand has conveyed his intention to step down as the LSIF Chair after a very successful 10 year term. She said the LSIF is now looking for a new chair and will be sharing nomination procedures with economies in the near term. The Chair LSIF PG observed that Minister Suwit had been a beacon for moving the LSIF forward. Under his leadership the group has become a world-renowned forum leading on interesting and diverse topics. No action would be taken, however, until Minister Suwit had formally advised the Board of his intention to step down.

ACTIONS:

(1) H.E. Suwit to formally advise the Board of his intention to step down as Chair
(2) Additional steps will be taken on receipt of the letter by the Board.

16. RHSC Updates

- See *APEC RHSC Meeting Agenda* (2013/SOM1/LSIF/017)
- See *RHSC Report* (2013/SOM1/LSIF/018)

The RHSC continues to make good progress towards its goal of achieving regulatory convergence by 2020. The RHSC was successful in securing close to $0.5 million through a multi-year funding proposal submitted by the US that will enable the effective implementation of the roadmap on Global Medical Product Quality and Supply Chain Integrity, thereby allowing APEC

to serve as a catalyst for international action under the direction of an oversight committee that includes major international partners, such as the WHO, the European Directorate for the Quality of Medicines (EDQM), and the European Medicines Agency. The roadmap foresees the implementation of a multi-faceted strategy that will address all the major elements necessary for promoting medical product integrity and supply chain security for both drugs and medical devices, including in vitro diagnostics (components and finished devices), informed by a gap analysis currently under development. One of the first offerings under the roadmap is the workshop on Public Awareness and Establishing a Single Point of Contact, to be held in Seoul May 22-23, 2013 in collaboration between the APEC Harmonization Center (AHC) and APEC Technical Assistance & Training Facility, building on previous APEC workshops to promote safe medical products and combat counterfeit/falsified products.

The delivery of a successful, first of its kind advanced workshop in November 2012 on Good Review Practices (GRevPs) that will lead to the development of a normative document and annual curriculum on the topic. Under the leadership of Chinese Taipei, discussions included the critical elements of a good review, quality managements systems, critical decision-making and transparency and interaction with stakeholders and other regulators, led by regulatory experts from the US, Japan, Europe, Canada, Chinese Taipei and other economies.

A jointly sponsored APEC- AHC – Asian Harmonization Working Party workshop on Combination Products , co-hosted by the TFDA of Chinese Taipei and the AHC in November 2012, with the aim of identifying current challenges, issues and best practices associated with the registration of combination products in the APEC region. Next steps include the prioritization and refinement of a strategy (roadmap) based on the results of the workshops and a survey underway.

The Thai FDA led completion of the Good Clinical Practices Inspection survey.

The objectives for the RHSC meeting being held February 1-2, 2013 were also presented. The first objective for the meeting is to manage the effective implementation of roadmaps in addressing the regulatory gaps. This means moving beyond workshops and high level meetings that identify challenges and set policy directions to multi-stakeholder implementation activities designed to advance progress for priority work areas, as expected by APEC Senior Officials.

Second, the RHSC will discuss working on implementing effective project management tools and processes towards this end.

Third, the RHSC will discuss establishing an APEC-wide Regulatory Network that will promote the participation of regulatory authorities from all 21 APEC Economies, together with industry, academia and regional and international organizations in RHSC endorsed activities.

Fourth, the RHSC will discuss launching a robust RHSC website to promote achievements, engagement and work processes.

Fifth, the RHSC will discuss implementing a more effective approach to training through the adoption of "Training Best Practices", technology and partnerships.

Of special mention is the proposal to establish of a Center of Excellence (COE) and a Network for Multi-regional Clinical Trials (MRCT) would serve to effectively implement the existing MRCT roadmap, under the stewardship of Japan and cooperation of the AHC, thereby addressing key hurdles to global trials and drug development. This would represent an important step in the MRCT Roadmap and have potentially significant implications for advancing life sciences innovation and access to important new therapies within the APEC region and on a global scale.

Other important objectives include the review and endorsement of a new roadmap on Cellular Therapies championed by Singapore as well as refined roadmaps on Biotechnological Products and Pharmacovigilance (Champion: Republic of Korea), Good Review Practices (Champion: Chinese Taipei) and an APEC Concept Note submitted by Thailand to promote regulatory convergence of Good Clinical Practices Inspection in the form of a 3 day workshop in Bangkok as a step in building capacity and best practices under the GCP Inspection roadmap (Champion: Thailand).

ACTION: RHSC Chair to report on the February 1-2, 2013 RHSC meetings intersessionally, including plans for establishing a regulatory network and possible plans for establishing an MRCT Center of Excellence for regulatory sciences

17. **LSIF Anti-counterfeit Medicines Action Plan and Workshop**

- See *Update on Progress Implementing the LSIF Anti-Counterfeit Medicines Action Plan* (2013/SOM1/LSIF/009)
- See *Announcement of Workshop on Medical Products Safety and Public Awareness and Establishing "Single Point of Contacts (SPOCs)" System (*2013/SOM1/LSIF/010)
- See *Detection Technology Best Practices Presented During 27-28 September 2011 APEC Drug Safety and Detection Technology Workshop* (2013/SOM1/LSIF/011)
- See *International Workshop on Patient Safety and Drug Detection Technology* (2013/SOM1/LSIF/012)

The United States presented an update on progress implementing the LSIF Anti-Counterfeit Medicines Action Plan. The United States provided an overview of the APEC LSIF Drug Safety and Detection Technology Workshop held in September 2011 in Beijing, China and the India Patient Safety and Drug Detection and Authentication Technology Workshop held in September 2012 in New Delhi, India.

The United States also spoke about the upcoming Workshop on Medical Products Safety and Public Awareness and Establishing of a "Single Point of Contacts (SPOCs)" System to be held 22-23 May 2013 in Seoul, the Republic of Korea. The organizers include the APEC LSIF, the APEC Harmonization Center (AHC), the APEC LSIF Regulatory Harmonization Steering Committee

(RHSC), the Korea Food and Drug Administration (KFDA) and the APEC Technical Assistance & Training Facility (APEC TATF). The workshop for government officials and relevant stakeholders will cover the following two topics: 1) falsified/counterfeit medicines public awareness; and 2) establishment of an APEC "Single Point of Contacts (SPOCs)" system for cooperation on public awareness and criminal investigations of falsified medicines. The workshop will build upon previous APEC workshops and seminars to promote safe medical products and to combat counterfeit/falsified medical products. The May 2013 workshop is also an activity of the RHSC Roadmap on Global Medical Product Quality and Supply Chain Integrity.

There is no registration fee for participants to attend the May 22 - 23 workshop, however, space is limited, so eligible participants are encouraged to submit the registration form located on the workshop website as soon as possible. APEC economies should consider being represented from various Ministries, including regulators, customs, law enforcement, other appropriate government officials and industry representatives. Government and industry representatives from non-APEC economies are also invited to attend, pending APEC approval. The most current announcement, agenda and the registration forms can be located at the workshop website - www.APEC-AHC.org. The workshop will be held in English and interpretation will not be available.

ACTIONS:

(1) LSIF to promote the May SPOC workshop with governments and industry

(2) Indonesia to share the document establishing its Single Point of Contact with the Project Overseer

18. APEC Harmonization Center Update

- See *APEC Harmonization Center (AHC) Update* (2013/SOM1/LSIF/013)

Under the aegis of the APEC Life Sciences Innovation Forum (LSIF) and with the strategic direction provided by the Regulatory Harmonization Steering Committee (RHSC), the APEC Harmonization Center (AHC) serves to promote the implementation of harmonized standards and better access to the regulatory best practices by providing a platform for addressing priority issues and challenges. Entering its fifth year of operation, the AHC now aims to move away from a model of standalone workshops to an approach of multi-phase planning for established priority work areas in accordance with the *RHSC Strategic Framework Regulatory Convergence for Medical Products by 2020*.

The 2012 AHC Biosimilars Workshop, which has been endorsed by the LSIF, was hosted by the AHC with the sponsorship of PhRMA on April 3-4 with an optional visit to a local company on April 5. This workshop was carried out on the basis of the Biosimilars roadmap which was developed by Korea FDA. This workshop brought together representatives from Industry (local and global), US Pharmacopoeia (USP) and national regulatory agencies (NRAs), addressing challenges and opportunities to advance regulatory harmonization of biosimilar regulation on a

global scale. Eight NRAs from Europe, US, Korea, Canada, Singapore, China, Japan and Chinese Taipei presented and participated in the workshop with US FDA remotely participating via videoconferencing. As a follow up of 2009 AHC Biosimilars Workshop, the topics for this workshop covered the current status of global biosimilar regulatory landscape, challenges and expectations on regulating biosimilars, and the future tasks for achieving regulatory convergence on biosimilars. The report for this workshop, containing summaries of discussions, ideas and recommendations from each session, has been drafted and is to be endorsed by the RHSC of APEC LSIF. Also, the discussions from the regulators meeting during the workshop were presented during the WHO implementation workshop on SBPs which took place in Xiamen, China on May 28-30. WHO showed positive attention and interests in the result of the workshop.

AHC and RHSC jointly held the AHC/RHSC workshop for strategic assessment to achieve regulatory harmonization. The workshop proceeded together with RHSC meeting. Speakers delivered presentations on: the role of APEC LSIF to promote public health; segment that needs international regulatory harmonization; and the need to figure out projects. And the workshop stressed the need to trigger participation from developing economies and to build up the partnership with those nations since there is limit in the regulation function of single regulatory institution. In addition to that, there were discussions on the issues of establishing regulatory network and enhancing participation from industries by sectors (Medical device, Pharmaceuticals, Biotechnological products, Genetics). Also presentation were made on Champion nations' Roadmap and Concept Note regarding RHSC priorities work areas and also the in-depth discussions regarding the presentation.

The Pharmacovigilance Workshop was held 25-26 October in Seoul after it was endorsed in principle by the RHSC in order for regulatory harmonization of PV, one of RHSC's priorities work areas. This Roadmap is led by Korea FDA and ongoing with received input from APEC economies. In the workshop, discussions were made on the current status of ICH and EU regarding Pharmacovigilance and the way of approach for regulatory harmonization by comparing regulations of APEC economies. Also the participants discussed what academic circle, industry and regulators should consider for regulatory harmonization. Through this they reached an agreement that Pharmacovigilance has been playing a critical role in assessing safety of medicines and voluntary reporting of adverse effect should be promoted and expanded through education for medical experts and patients.

In order for harmonizing regulatory process for combination product of medicines and medical devices, AHC held workshop at Chinese Taipei together with Chinese Taipei FDA, AdvaMed and AHWP. The workshop was held with annual AHWP conference, therefore participated by many experts from medical devices sector. It was also held after the endorsed in principle by the RHSC and there were presentations on regulatory trend of combination products and analysis on the current regulations in the APEC economies and also the discussions on major challenges and issues needed to be resolved for achieving regulatory harmonization. The workshop provided an opportunity for regulators to enhance their capacity in regulating combination products.

AHC website (www.apec-ahc.org) has been consistently providing educational opportunity to participants by uploading training materials and recorded videos presented during the four workshops held in 2012. In order to give all participants an opportunity to learn regardless of time and space, e-presentation system was built up and AHC website has been continuously renewed as part of an effort to harmonize regulatory process in the APEC economies.

For the purpose of enhancing the quality of education provided by AHC and helping the regulatory harmonization in the APEC region, AHC has been forging partnerships with various international organizations such as ICH, GHRF, AHWP and IFPMA. Especially Dr. Kui-lea Park of AHC was nominated as a representative of APEC to ICH GCG and presented the activities of AHC at ICH Fukuoka meeting on June 2012 and San Diego meeting on Nov 2012. AHC Advisory Board includes 23 internationally renowned experts. AHC will expand the scope of the experts and economies thus providing opportunity of excellent education by incorporating inputs from the experts.

19. Working with ABAC

The Advisor to the LSIF Co-Chairs provided an overview of the APEC Business Advisory Council (ABAC). The ABAC is a group of private sector leaders appointed by their respective Head of State to provide advice on challenges facing the business community in the region and how APEC could help address those challenges. The ABAC is composed of three private sector representatives from each APEC member economy. The ABAC meets four times per year including during the APEC Leaders' Week at the end of the APEC year. In 2012, APEC Ministers called on APEC Economies to increase constructive involvement of the private sector in APEC processes and encourage further substantial collaboration with ABAC and other stakeholders. In September 2012, the United States appointed Mr. Bart Peterson, Senior Vice President, Corporate Affairs and Communications, Eli Lilly and Company, to represent the United States on the APEC Business Advisory Council (ABAC). This is the first time a representative of the health industry has been appointed to the ABAC. The Chair LSIF PG observed that it would be helpful to work with ABAC going forward.

ACTIONS:

(1) Include reports from ABAC meetings in the LSIF Planning Group Agenda

(2) Inform ABAC of LSIF work programs.

Conclusion

The Chair LSIF PG thanked the participating APEC economies for their contributions and closed the meeting.