



**Asia-Pacific
Economic Cooperation**

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Agenda Item: VI x

Life Sciences Innovation Forum Convenor Report

Purpose: Information
Submitted by: LSIF Convenor



**Third Committee on Trade and Investment
Meeting
24-26 August 2021**

LIFE SCIENCES INNOVATION FORUM CONVENOR'S SUMMARY REPORT TO CTI 3 2021

1. During 2021, how has the forum's work contributed to CTI's objectives of:

a. Support for the Multilateral Trading System

b. Regional Economic Integration, including taking forward the Putrajaya Vision 2040 and contributing to the development of the Implementation Plan in 2021

LSIF advances several aspects of the Putrajaya Vision 2040.

Trade and Investment

"To ensure that the Asia-Pacific remains the world's most dynamic and interconnected regional economy, we acknowledge the importance of, and will continue to work together to deliver, a free, open, fair, non-discriminatory, transparent and predictable trade and investment environment."

- LSIF promotes a free, open, fair, non-discriminatory, transparent and predictable trade and investment environment for life sciences and medical products through its [Regulatory Harmonization Steering Committee \(RHSC\)](#), which helps to implement the WTO Technical Barriers to Trade (TBT) Agreement.
- In 2021 LSIF endorsed [RHSC Vision 2030 and Strategic Framework](#), which includes a common vision to accelerate regulatory convergence for medical products in the APEC region as much as possible by 2030. Regulatory convergence is a voluntary process whereby regulatory requirements across economies become more aligned over time as a result of the adoption of internationally recognized technical guidances, standards and best practices. The WTO TBT Agreement strongly encourages members to base their measures on international standards as a means to facilitate trade.
- There are currently 29 [APEC LSIF RHSC Training Centers of Excellence for Regulatory Science](#) across 9 economies conducting training to build skilled human capacity at scale to support the adoption of internationally recognized technical guidances, standards and best practices. In 2021 LSIF RHSC will execute 21 such trainings:

1	Advanced Therapy Products	Pilot CoE	USP
2	Advanced Therapy Products	CoE	NEU
3	Biotherapeutic Products	CoE	NEU
4	Global Supply Chain Integrity	CoE	Taylor's University & USP
5	Good Registration Management	CoE	TFDA
6	Good Registration Management	CoE	TFDA
7	Medical Devices	CoE	USC
8	Medical Devices	CoE	SCU
9	Medical Devices	CoE	PMDA
10	Medical Devices	CoE	NIDS
11	Medical Devices	CoE	TFDA
12	Medical Devices	CoE	SCH
13	Medical Devices	Pilot CoE	NEU
14	MRCT/GCP	CoE	PMDA (& NCC Japan)
15	MRCT/GCP	CoE	PKU
16	MRCT/GCP	CoE	MRCT Center
17	MRCT/GCP	CoE	MRCT Center
18	MRCT/GCP	CoE	KoNECT
19	Pharmacovigilance	CoE	PMDA
20	Pharmacovigilance	CoE	PKU
21	Pharmacovigilance	CoE	KIDS

- In 2021 LSIF RHSC will also execute policy dialogues in collaboration with the APEC Harmonization Center on topics such as:
 - “Facilitated Regulatory Pathways” (September)
 - “Post-Pandemic Regulatory Innovation & Convergence for Medical Devices” (October)
 - “Post-Pandemic Regulatory Innovation & Convergence for the Biopharmaceutical Sector (October)

Innovation and Digitalisation

“To empower all our people and businesses to participate and grow in an interconnected global economy, we will foster an enabling environment that is, among others, market-driven and supported by digital economy and innovation.”

- LSIF promotes networking, best practices sharing and collaboration among researchers, industry and government in the life sciences sector, thereby empowering interconnected, innovation global ecosystems that are able to commercialize new ideas and bring them to market in the APEC region.

Strong, Balanced, Secure, Sustainable and Inclusive Growth

“To ensure that the Asia-Pacific region is resilient to shocks, crises, pandemics and other emergencies, we will foster quality growth that brings palpable benefits and greater health and wellbeing to all, including MSMEs, women and others with untapped economic potential.”

- LSIF has and continues to support the region’s ability to bring treatments and vaccines to market, allowing the region to respond to current and future

pandemics and promote quality growth that brings palpable benefits and greater health and wellbeing to all.

- In 2021 LSIF endorsed the [APEC Action Plan on Vaccination Across the Life-Course](#) to serve as a comprehensive strategy for enhancing the resilience and sustainability of immunization programs in the APEC region. The COVID-19 pandemic underscores the urgency of protecting populations and ensuring the highest coverage against vaccine-preventable diseases.

c. Trade Facilitation and Connectivity

LSIF supports APEC as a whole and members individually in reducing and eliminating unnecessary barriers to trade in medical products and in promoting resilient supply chains for medical products. As noted earlier the LSIF promotes regulatory cooperation and convergence.

The LSIF continues to work with APEC members and its network of APEC Training Centers of Excellence for Regulatory Science to ensure the wide dissemination of the [APEC Supply Chain Security Toolkit for Medical Products](#) and to promote the adoption of best practices by industry stakeholders and regulators throughout the region.

d. Inclusion

LSIF continues to address barriers to the deployment of innovative healthcare financing mechanisms, which enhance access to greater health and wellbeing to all. In 2021 LSIF held three workshops examining issues such as increasing the use financial services including insurance; innovative digital, fintech, and insurtech solutions, and the role of impact investors attracting nearly 500 participants.

LSIF facilitates the sharing of policies and best practices to reduce barriers to healthcare services for people living with a rare disease and caregivers, and to harness digital technologies to drive innovation in rare disease diagnosis, treatment, and management. In 2021 LSIF will hold 4 workshops examining issues such as orphan drug policy, newborn genetic screening, and patient registries, among others.

LSIF co-hosts with the Health Working Group (HWG) the APEC Digital Hub for Mental Health.

e. Any other issues

2. **How has the forum helped to fulfil the mandate of the [2021 Ministers Responsible for Trade Statement](#) & [2020 Declaration on Facilitating the Movement of Essential Goods by the MRT](#) (see Appendix B)**

The 2021 MRT Statement stated: “Defeating COVID-19 is the top priority for every economy. Recognising the role of extensive COVID-19 immunisation as a global public good, we urgently need to accelerate the production and distribution of safe, effective, quality-assured, and affordable COVID-19 vaccines.”

- Swift regulatory approvals are critical to the distribution of safe, effective, quality-assured, and affordable COVID-19 vaccines. As noted, the LSIF is accelerating efforts to advance regulatory convergence and avoid unnecessary duplication of regulatory reviews thereby allowing products to be approved more quickly.
- The LSIF developed the [APEC Action Plan on Vaccination Across the Life-Course](#) to serve as a comprehensive strategy for enhancing the resilience and sustainability of immunization programs in the APEC region. The COVID-19 pandemic underscores the urgency of protecting populations and ensuring the highest coverage against vaccine-preventable diseases.
- The LSIF is working to facilitate the sharing of information and best practices in harnessing the digital economy and digital technologies to enable the future of life sciences innovation and our ability to address COVID-19 and future health challenges.

The 2021 MRT Statement stated: “Noting the detrimental impact of border and travel restrictions on our people and our economies, we must pave the way for the safe resumption of cross-border travel, without undermining efforts to prevent the spread of COVID-19....We direct officials to discuss how APEC can better support air crews, facilitate business mobility across the region, and advance discussions on digital solutions to facilitate safe travel in the region, and report on progress before our APEC Ministerial Meeting in November.”

- The LSIF has circulated a self-funded project “Exploring Health Technologies to Restoring Cross-Border Travel in APEC Post-COVID-19” to convene relevant economic, health, travel/transport/tourism and customs/border authorities, along with the private sector (e.g., airlines, airport/travel operators, test and vaccine manufacturers, digital technology developers) virtually to exchange views and share technologies that can be used to facilitate the resumption of travel, accounting for the specific pandemic conditions facing each APEC economy.

3. Main outcomes from most recent plenary meeting

- Endorsement of [RHSC Vision 2030 and Strategic Framework](#) and welcoming of new APEC Training Centers of Excellence for Regulatory Science bringing the total to 29 centers hosted at 20 institutions across nine APEC economies.
- Endorsement of the [APEC Action Plan on Vaccination Across the Life Course](#) and welcoming of outcomes from multiple policy dialogues and webinars as well as planned work on sustaining strong vaccine supply chains.
- Endorsement of the [APEC Healthcare Financing Roadmap](#) and welcoming of the outcomes from the webinar series which as involved nearly 500 participants to date.

4. Private sector engagement in 2021

As a tripartite forum, the LSIF engages the private sector in all of its work. For instance, the RHSC designates industry coalition coordinators to represent the views of the innovative research-based pharmaceutical sector, generic manufacturers, medical device sector, and

advanced therapy (cell, gene, and tissue-based therapy) sector. Private sector representatives serve on the planning committee and as faculty for trainings conducted by the [APEC LSIF RHSC Training Centers of Excellence for Regulatory Science](#). Also for example, the LSIF Rare Disease Network includes in its leadership an Industry Co-Chair (in addition to Government and Academic Co-Chairs) and includes in its membership an Industry Coalition comprised of biopharmaceutical companies that manufacture rare disease therapies.

5. Cross-fora collaboration in 2021

- LSIF collaborated with the Health Working Group (HWG) on the 11th APEC High-Level Meeting (LSIF) on Health & the Economy and endorsement of the joint statement.
- LSIF collaborated with the Health Working Group (HWG) on the APEC Action Plan on Vaccination Across the Life Course.
- LSIF continues to collaborate with the Health Working Group (HWG), Finance Ministers' Process (FMP), the APEC Business Advisory Council (ABAC), and the Asia-Pacific Financial Forum (APFF) to address barriers to the deployment of innovative healthcare financing mechanisms.
- LSIF has advised the APEC Sub-Committee on Customs Procedures (SCCP) on good import practices for medical products as outlined in the APEC LSIF Supply Chain Security Toolkit.
- The LSIF circulated a self-funded project "Exploring Health Technologies to Restoring Cross-Border Travel in APEC Post-COVID-19" to the Business Mobility Working Group, Tourism Working Group, Transportation Working Group, and Health Working Group for input.

6. Was quorum¹ reached at the most recent plenary meeting?

Quorum was reached with 16 economies participating.

7. Taking into consideration the forum's Assessment Report, what is your Forum doing to maintain/increase its relevance to APEC member economies and increase participation from its members?

The LSIF is continuing its close collaboration with the Health Working Group and other relevant APEC groups to increase efficiency and avoid duplication of efforts while maintaining a focus on trade, economic, and investment issues as they relate to the life sciences sector.

8. Decision points needed from CTI

- Seek CTI's endorsement of the LSIF Convenor's Report.

¹ Quorum requires 14 economies or more. Quorum is measured by member economies (not including private sector) participating. Remote participation is counted.

APPENDIX A

FORUM'S CONTRIBUTION TO CTI'S OBJECTIVES

Appendix A provides examples of work that contributes to CTI's objectives

Support for the Multilateral Trading System

Initiatives that support:

- The multilateral trading system as embodied by the World Trade Organization (WTO) including the 12th WTO Ministerial Conference
- The implementation of WTO Agreements / Decisions

Regional Economic Integration

Initiatives that support:

- Achievement of *the Putrajaya Vision 2040* and development of its Implementation Plan/Action Agenda
- Eventual realization of the Free Trade Area of the Asia Pacific (FTAAP)
- Next Generation Trade and Investment Issues
- Internet and Digital Economy, E-Commerce and Digital Trade
- Global Value Chain Cooperation and Development
- MSMEs' Internationalization
- Environmental Goods and Services/Green Growth
- Services, including implementation of the APEC Services Competitiveness Roadmap
- Investment
- Market Access and reducing impact of Non-tariff Measures
- Intellectual Property
- Business Mobility through e.g. APEC Business Travel Card

Trade Facilitation and Connectivity

Initiatives that support:

- Supply Chain Connectivity, including implementation of Phase II of the Supply Chain Framework Action Plan (SCFAP II), GVC Blueprint 2.0
- Trade Facilitation, including work that supports implementation of the WTO Trade Facilitation Agreement
- Connectivity
- Regulatory Cooperation and Convergence

Inclusion

Initiatives that support:

- Implementation of the Action Agenda on Economic, Financial and Social Inclusion

APPENDIX B

Extracts from 2021 Ministers Responsible for Trade Statement & the 2020 Declaration on Facilitating the Movement of Essential Goods by the MRT

Facilitating the Movement of Essential Goods

Export Restrictions and Prohibitions

- Each APEC economy will ensure that any emergency trade measures designed to tackle COVID-19 are consistent with WTO rules.
- Each APEC economy will ensure that any trade measure introduced in response to COVID-19 is notified in accordance with relevant WTO obligations.

Non-Tariff Barriers

- APEC economies are encouraged to work together to identify and resolve any unnecessary barriers to trade in essential goods.

Trade Facilitation

- Each APEC economy, consistent with its obligations under the WTO Agreement on Trade Facilitation, should expedite and facilitate the flow and transit of essential goods.
- APEC economies remain committed to enhance coordination, efficiency and transparency of the border clearance of essential goods, and full implementation of the WTO Agreement on Trade Facilitation, to help facilitate trade.
- Each APEC economy should endeavour to expedite the release of essential goods upon arrival, including adopting or maintaining procedures allowing for submission of import documentation and other required information, such as manifests, in order to begin processing prior to the arrival of goods.
- Each APEC economy will endeavour to facilitate the entry, transit and departure of air cargo containing essential medical supplies.
- APEC economies are expected to abide by the International Health Regulations (IHR) (2005)

Tariffs

- APEC economies take note of ABAC's recommendation for economies to take tariff liberalisation measures for essential medical supplies

APEC Ministers Responsible for Trade Meeting Joint Statement 2021

Medical supplies:

Today, we are pleased to announce a standalone statement on COVID-19 Vaccine Supply Chains (Annex 1), which outlines our approach to ensuring the trading environment supports the safe and efficient distribution of COVID-19 vaccines and related goods. We welcome the *Best Practice Guidelines for APEC Customs Administrations* as an operational and practical contribution to help facilitate the distribution of COVID-19 vaccines and related goods. To continue APEC's strong work in responding to the challenges of COVID-19, APEC economies will also agree to consider how to facilitate trade in medical supplies such as those included in the World Customs Organization (WCO) COVID-19 list,² and report to us before our APEC Ministerial Meeting in November.

Digital:

... we will accelerate implementation of the WTO Trade Facilitation Agreement, particularly those articles relating to: the accelerated use of digitalisation for border processes; pre-arrival processing of electronic declarations; electronic documents, electronic certification, electronic payments; expedited shipments; and border agency cooperation.... We agree to embed digital trade facilitation measures taken by APEC members during COVID-19. We task officials to report on progress when we meet again at the APEC Ministerial Meeting in November

² [World Customs Organization: HS classification reference for Covid-19 medical supplies](#)

APEC MRT Statement on COVID-19 Vaccine Supply Chains (Annex 1)

Vaccines statement: Review Mechanism:

The APEC Secretariat will make a summary report on the actions implemented by economies under this initiative by the APEC Ministerial Meeting in November 2021

- use the WCO-WHO list of COVID-19 vaccines and related goods as a reference for facilitating trade. APEC economies will expedite the flow and transit of all COVID-19 vaccines and related goods through their air, sea and land ports. We will expedite their release upon arrival, including by providing for advance electronic submission and processing of information to enable immediate release upon arrival.
- advance the implementation of the *Best Practice Guidelines for APEC Customs Administrations to Facilitate the Distribution of COVID-19 Vaccines and Related Goods*. We agree to embed the trade facilitation measures implemented during the pandemic, including digitising customs procedures, expediting the flow of goods across borders, and boosting coordination between traders and border agencies.
- While WTO rules permit export restrictions or prohibitions in certain circumstances, we emphasise economies who adopt such measures with respect to COVID-19 vaccines and related goods will evaluate their ongoing necessity as COVID-19 conditions change, in order to ensure they remain targeted, proportional, transparent, temporary, and do not create unnecessary barriers to trade.
- We will consider voluntary actions to reduce the cost of these products for our people, particularly by encouraging each economy to review its own charges levied at the border on COVID-19 vaccines and related goods.
- We will take appropriate measures to prevent criminal exploitation of supply chains and to prevent the entry and import of illegal, dangerous, sub-standard or counterfeit COVID-19 vaccines and related goods. This could include further implementing the *APEC Roadmap to Promote Global Medical Product Quality and Supply Chain Security and related toolkit*.