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| 17 September 2019 |
| Asia-Pacific Economic Cooperation (APEC)  Life Sciences Innovation Forum (LSIF) |
| Report of the  Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence    “A Decade of Regulatory Convergence in APEC: Learning from the Past, Looking to the Future” |
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| **18 August 2019** |

Puerto Varas, Chile

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# Purpose

This report serves as a summary of outcomes from the APEC Life Sciences Innovation Forum (LSIF) Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence (PD), held 18 August 2019 in Puerto Varas, Chile, including recommendations for consideration by the APEC High Level Meeting on Health & the Economy (HLM), APEC Ministers, and APEC Leaders.

# Background

The PD was organized by the LSIF under the leadership of Ms. Erika Elvander (LSIF Planning Group Chair) with support from the APEC Harmonization Center (AHC) under the leadership of Dr. Dong-hee Lee (Director) and from Chile as the APEC 2019 Host Economy.

The PD built upon the LSIF’s long-standing recognition of the critical role that the life sciences sector plays in promoting public and economic health and the role that strong and efficient regulatory systems play in enabling life sciences innovation.

The PD convened the leaders of drug and medical device regulatory authorities and representatives from industry and academia to reflect on a decade of progress towards regulatory convergence[[1]](#footnote-1) in APEC and to envision the next iteration of a regional vision for how regulatory systems and regulatory convergence may accelerate life sciences innovation and make new medical products available to populations across APEC economies.

*See Annex 1 for the agenda of the PD as executed on 18 August 2019 in Puerto Varas, Chile.*

# Outcomes

1. **The PD concluded with a strong affirmation that the RHSC should continue its work beyond 2020 and accelerate APEC’s regulatory convergence efforts** for a number of key reasons:
   1. Regulatory convergence **protects people’s safety**: when we take advantage of testing, inspections, and reviews already done by high-performing regulators around the region, we can efficiently ensure approved products are both effective and safe, and work together to watch for safety issues in our collective population.
   2. Regulatory convergence **makes products available**: when we leverage the assessment work already done by high-performing regulators on a particular life-saving product, we can approve that product more quickly and ensure it is readily available on the market to those who need it.
   3. Regulatory convergence **saves public resources**: when we tap into the expertise and work of other high-performing regulators around the region, we can avoid unnecessary duplication and limit wasteful spending so we save our precious public health resources for use elsewhere.
   4. Regulatory convergence **attracts investment**: when we shorten burdensome procedures and adopt best practices by trusting the processes of high-performing regulators, we can reduce uncertainty and delays so that both local and international firms find it easier to do business in our economies, invest their capital, and create jobs.
   5. Regulatory convergence **prevents corruption**: when we avoid duplicate inspections and lengthy approval procedures, we can reduce the time it takes to respond to an application, so we prevent opportunities for corrupt or dishonest behavior.
   6. Regulatory convergence **improves global standing**: when we share the load with other regulators and join international initiatives, we show our willingness to cooperate and support best practices, which strengthen the global community and enable investment in our economies.

The PD therefore strongly reaffirmed the statement made by APEC Ministers in 2011 to “…achieve convergence on regulatory approval procedures for medical products by 2020, which will allow patients more timely access to innovations” and **urged** **an extension and acceleration of efforts to meet the convergence goal by 2030**.

Looking ahead to 2030, the PD participants **encouraged the RHSC to consider the following additions to its strategy for the next decade:**

1. Establishing a ‘regulatory sandbox’ to enable piloting innovative regulations;
2. Supporting ‘horizon scanning’ exercises led by regulators with experience in novel products;
3. Interacting with patients, healthcare providers, and political leaders including legislators ;
4. Improving participation from APEC member economies in RHSC meetings and activities; and,
5. Improving outreach and communications both within and outside of APEC; and,
6. Improving connection to other regulatory harmonization initiatives and mechanisms such as ICH, IPRP, PIC/S, IMDRF, PANDRH, and MDSAP.
7. **PD participants reflected on RHSC key performance indicators (KPIs)[[2]](#footnote-2) tracking regulatory convergence over the last decade and now on an annual basis (conducted as an LSIF-AHC Project).**

Endorsed in 2017, the KPIs measuring progress towards achieving regulatory convergence include:

* 1. Number of economies engaging in information sharing;
  2. Number of economies establishing confidentiality commitments;
  3. Number of economies sharing Good Manufacturing Practices (GMP) certificates;
  4. Number of economies establishing Mutual Recognition Agreements (MRAs);
  5. Number of economies minimizing required Certificates of Pharmaceutical Product (CPPs);
  6. Number of economies allowing multiple sites in a single license; and,
  7. Number of economies joining regulatory harmonization initiatives including the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), Pharmaceutical Inspection Cooperation Scheme (PIC/S), and International Pharmaceutical Regulators Programme (IPRP).

The PD participants acknowledged that the KPIs endorsed by RHSC to date are focused on regulatory convergence of drug and vaccine approvals, and **welcomed KPIs to monitor and evaluate regulatory convergence of medical device approvals as well.** The PD participants encouraged the RHSC to not only continue tracking the KPIs on an annual basis, but also to **develop more specific KPIs to track progress within each priority work area (PWA).**

The PD participants emphasized that KPIs should not be used to single out economies but, rather, should be used to **ensure that “no economy is left behind” in support of “inclusive growth”.**

*See Annex 2 for an illustration of KPI data collected and analyzed by AHC, from 2008 to 2019.*

1. **PD participants reflected on the next decade of a regional vision for how regulatory systems and regulatory convergence may accelerate life sciences innovation and make new medical products available to populations across APEC economies.** Leaders of regulatory authorities and other PD participants urged the RHSC to consider focusing new efforts on:
   1. Reliance on stringent regulatory authorities;
   2. Creation and expansion of expedited or facilitated regulatory pathways;
   3. Use of third-party reviews for low-risk medical devices;
   4. Collection and use of real world evidence;
   5. Digital technologies (for research and development); and,
   6. Patient-centered drug development.
2. **PD participants applauded the RHSC for continuing to improve and scale its network of Training Centers of Excellence for Regulatory Science (CoEs) to build skilled human capacity, and urged regulatory authorities to send participants and also provide support in the form of faculty**. PD participants noted that CoEs will continue to serve as a key pillar to advancing the RHSC’s regulatory convergence goal.

It was also noted that the CoE network complements ICH and IMDRF by helping supporting the gradual adoption of internationally recognized technical guidance documents, standards and scientific principles through training. As of 2019 across nine APEC economies there are 16 Centers of Excellence hosting 23 workshops this year, which will train hundreds of regulators.

The PD participants encouraged RHSC and CoEs to **develop and track KPIs to measure not only the outputs and outcomes of training activities, but their impact both the short- and long-term.** Improving the impact of training activities may also require renewed focus on developing consistently recurring, long-term programs to teach and test students instead of single, *ad hoc* programs.

The PD participants urged RHSC and CoEsto **consider strategies to increase the geographic diversity and reach of training programs, such as through ‘roadshows’ and other traveling or remote programs, as well as strategies to improve the financial sustainability of programs.**

*See Annex 3 for CoEs that have been endorsed by the RHSC and are now operational, as well as pilots for additional CoEs have been endorsed by the RHSC.*

1. **PD participants concluded that all relevant stakeholders – among them regulators and regulated industry – should appropriately prioritize and resource regulatory convergence efforts within the context of their own economies.** This includes promoting the use of existing international guidelines, supporting a strategic and coordinated approach to regulatory convergence, and building human and regulatory capacity, such as the approach taken by the RHSC and its partners such as the LSIF and AHC.

In addition, stakeholders should promote complementary action and make maximum use of resources, for example by maintaining a focus on using the ICH, IMDRF, and others to develop guidelines while leveraging RHSC to implement such guidance by building skilled human capacity.

1. **The PD included a session on “Innovation and Regulatory Convergence from Beyond APEC” with invited guests from Brazil, Colombia, and the Pan American Health Organization, and reflected on future collaboration and coordination with non-APEC economies** in areas such as:
   1. Sharing training opportunities with non-APEC economies as interested parties;
   2. Special briefings for regulatory authorities and leaders in non-APEC economies; and,
   3. Standing invitations for non-APEC economies to observe RHSC meetings.
2. **PD participants thanked AHC for its support over the last decade for pilot CoEs and other training programs, workshops, and the CoE website; and asked the AHC to continue their involvement in the RHSC**, focusing their efforts on assisting pilot CoEs, organizing special workshops, and helping lead strategic and high-level projects such as the survey and analysis of the KPIs.

# Annex 1: Agenda

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| 8:30-9:00 | Arrival, Registration, and Networking |
| 9:00-9:20 | **Opening Remarks**   * **Ms Erika Elvander**, Chair, APEC LSIF Planning Group; Director, Asia-Pacific, Office of Global Affairs, Department of Health and Human Services, The United States * **Mr Carlos Bravo Goldsmith**, Head, National Medicines Agency Department (ANAMED), Chile * **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea |
| 9:20-10:20 | **Setting the Scene: APEC Progress Towards Regulatory Convergence**  This session will showcase the results of the joint AHC–LSIF project to track key performance indicators (KPIs) measuring progress towards regulatory convergence among APEC economies. How have we performed? Where might future efforts be focused? Are we tracking the right KPIs?  (*Moderator*) **Ms Patricia Wu**, LSIF Advisor   * **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea * **Prof John Lim,** Professor & Executive Director, Center for Regulatory Excellence (CoRE), Duke-National University of Singapore |
| 10:20-10:30 | Official Photograph & Coffee/Tea Break |
| 10:30-12:00 | **Session 1: Keynote Remarks from Regulatory Authorities**  This session will explore diverse perspectives on how APEC regulatory authorities are accelerating regulatory convergence, their reflections on a decade of regulatory work in APEC, and their thoughts on future efforts.  (Co-*Moderators*) **Dr Michelle Limoli**, Co-Chair, APEC RHSC; Senior International Health Science Advisor, Food and Drug Administration, The United States; **Dr Nobumasa Nakashima**, Co-Chair, APEC RHSC; Senior Director for International Programs, Pharmaceutical and Medical Device Agency, Japan   * **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea * **Datin Dr Faridah Aryani Binti Md. Yusof**, Head, National Pharmaceutical Regulatory Authority, Malaysia * **Dr Oscar Guitierrez**, Officer-in-Charge, Policy & Planning Service, Food and Drug Administration, The Philippines * **Dr Shou-Mei Wu**, Director General, Taiwan Food and Drug Administration, Chinese Taipei |
| 12:00-13:30 | Lunch |
| 13:30-14:30 | **Session 2: Lessons on Innovation & Regulatory Convergence from Beyond APEC**  This session will present unique perspectives, insights, and best practices from neighboring non-APEC economies on their own efforts to accelerate life sciences innovation and to promote regulatory convergence regionally and globally.  (*Moderator*) **Mr Carlos Bravo Goldsmith**, Head, National Medicines Agency Department, Chile   * **Ms Daniela Marreco Cerqueira**, Deputy Director, National Health Surveillance Agency (ANVISA), Brazil * **Ms Judith Mestre**, Director of Medicines and Biologic Products, National Institute of Food & Drug Surveillance (INVIMA), Colombia * **Mr Rafael Díaz-Granados**, Executive Director, Latin American Federation of Pharmaceutical Industry (FIFARMA) * **Dr James Fitzgerald**, Director, Health Systems and Services, Pan American Health Organization (PAHO) |
| 14:30-16:00 | **Session 3: Industry Perspectives on Regulatory Convergence & the Future of Health Care**  This session will examine how medical products industries are accelerating regulatory harmonization, how progress benefits consumers and patients, their reflections on a decade of regulatory convergence in APEC, and their thoughts on future efforts in APEC.  (*Moderator*) **Ambassador Robert Holleyman**, President & CEO, Crowell & Moring International  **Medical Devices**   * **Ms Nicole Taylor Smith**, APEC RHSC Medical Device Industry Coalition Member; Vice President, Medtronic * **Mr Naoki Morooka**, APEC RHSC Medical Device Industry Coalition Coordinator; Vice Division Chairman, Regulatory & Safety, Japan Medical Imaging & Radiological Systems Industries Association (JIRA)   **Research-Based Pharmaceuticals & Biotechnological Products**   * **Ms Camille Jackson**, APEC RHSC Research-Based Pharmaceutical Industry Coalition Coordinator; Associate Vice President, Pharmaceutical Researchers & Manufacturers of America (PhRMA) * **Mr Kazuharu Matsuoka**, APEC RHSC Research-Based Pharmaceutical Industry Coalition Coordinator; Director, Japan Pharmaceutical Manufacturers Association (JPMA) * **Ms Lila Feisee**, APEC RHSC Biotechnological Products Industry Coalition Coordinator; Vice President, International Affairs, Biotechnology Innovation Organization (BIO) |
| 16:00-17:00 | **Session 4: Academic and Institute Perspectives**  In 2019, RHSC’s network of Training Centers of Excellence for Regulatory Science is expected to hold over 20 regulatory training programs, reaching hundreds of regulators. This session will highlight how these institutions are facilitating regulatory convergence through research, education, and capacity-building, their reflections on a decade of regulatory convergence in APEC, and their thoughts on future efforts in APEC.  (*Moderator*) **Dr Samvel Azatyan**, Group Lead, Capacity Building, Regulatory Systems Strengthening Team, World Health Organization (WHO)   * **Prof Gong Chen,** Secretary-General, APEC Health Science Academy, Executive Deputy Director, Institute of Population Research, Peking University * **Dr Jared Auclair**, Co-Chair, APEC RHSC Centers of Excellence Coalition; Associate Teaching Professor & Director, Northeastern University (NEU) * **Dr Ronald Piervincenzi**, Alternate Co-Chair, APEC RHSC Centers of Excellence Coalition; CEO, United States Pharmacopeia (USP) * **Mr Cherng Yeu Neo**, Co-Chair, APEC RHSC Centers of Excellence Coalition; Associate Director, Center of Regulatory Excellence (CoRE), Duke-National University of Singapore (Duke-NUS) |
| 17:00-17:50 | **Concluding Observations, Recommendations, and Remarks**  (*Moderator*) **Ms Erika Elvander**, Chair, APEC LSIF Planning Group; Director, Asia-Pacific, Office of Global Affairs, Department of Health and Human Services, The United States   * **Prof John Lim**, Professor & Executive Director, Center for Regulatory Excellence (CoRE), Duke-National University of Singapore * **Dr Mijeong Kim,** Cardiovascular & Neurology Products Division, National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety, Korea * **Dr James Fitzgerald**, Director, Health Systems and Services, Pan American Health Organization (PAHO) |

# Annex 2: Key Performance Indicators

# Annex 3: APEC Training Centers of Excellence for Regulatory Science

As of 2019 across nine APEC economies there are 16 Centers of Excellence hosting 23 workshops this year, which will train hundreds of regulators.

* **Multi-regional Clinical Trials (MRCT) and Good Clinical Practices (GCP) Inspection**

1. Duke-National University of Singapore (Duke-NUS) – Singapore
2. Peking University – P.R. China
3. Pharmaceuticals and Medical Devices Agency (PMDA) – Japan
4. MRCT Center of Brigham & Women’s Hospital and Harvard University – United States

* **Biotechnological Products (Biotherapeutics)**

1. Northeastern University – United States
2. APEC Harmonization Center – Republic of Korea
3. Duke-NUS – Singapore
4. Kobe University – Japan (***Pilot***)

* **Good Registration Management (GRM)**

1. Taiwan Food and Drug Administration (TFDA), Chinese Taipei in cooperation with Regulatory Affairs Professional Society (RAPS) – Chinese Taipei
2. COFEPRIS – Mexico
3. Thailand Food & Drug Administration (Thai FDA) – Thailand (***Pilot***)

* **Pharmacovigilance**

1. PMDA – Japan
2. Korean Institute for Drug Safety (KIDS) – Republic of Korea
3. Peking University – P.R. China

* **Global Supply Chain Integrity**

1. U.S. Pharmacopeia (USP) – United States
2. University of Tennessee Health Science Center – United States
3. Taylor’s University – Malaysia (***Pilot***)

* **Advanced Therapies (Cell, Gene, and Tissue-Based Therapies)**
  1. Northeastern University – United States
  2. Duke-NUS – Singapore
* **Medical Devices**

1. University of Southern California (USC) – United States
2. National Institute of Device Safety (NIDS) – Republic of Korea
3. PMDA – Japan (***Pilot***)
4. TFDA, Chinese Taipei in cooperation with RAPS – Chinese Taipei (***Pilot***)
5. Northeastern University – United States (***Pilot***)

1. The RHSC defines “regulatory convergence” as a voluntary process whereby the regulatory requirements across economies become more similar or “aligned” over time as a result of the gradual adoption of internationally recognized technical guidance documents, standards and scientific principles (harmonization) and common or similar practices and procedures. It does not represent the harmonization of laws and regulations, which is not necessary to allow for the alignment of technical requirements and for greater regulatory cooperation. [↑](#footnote-ref-1)
2. Chong, S.S.F., Lim, J.C.W. & Tominaga, T. “Developing key performance indicators to measure the progress of regional regulatory convergence and cooperation in APEC.” *AAPS Open* (2018) 4: 4. doi.org/10.1186/s41120-018-0024-2 [↑](#footnote-ref-2)