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Regulatory Harmonization Steering Committee Vision 2030 and Strategic Framework - Regulatory Convergence for Medical Products by 2030

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Asia-Pacific Economic Cooperation
Life Sciences Innovation Forum
(APEC LSIF)

Regulatory Harmonization Steering Committee
(RHSC)

Vision 2030
&
Strategic Framework

Regulatory Convergence for Medical Products by 2030

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1. Background

The Asia-Pacific Economic Cooperation (APEC) Life Sciences Innovation Forum (LSIF) and its Regulatory Harmonization Steering Committee (RHSC) adopted its strategic plan (*Vision 2020: A Strategic Framework: Regulatory Convergence for Medical Products by 2020*) in 2010 in Sendai, Japan. This strategic plan provided the basic proposal and rationale for achieving regional regulatory convergence of medical product approval procedures, which APEC Ministers reiterated in the Joint Ministerial Statement in 2011. While each APEC member economy adopted each phase on its own timeframe, the ultimate aim was for APEC economies to achieve as much regulatory convergence as possible by 2020.

Since 2010, the RHSC has facilitated a number of major accomplishments including but not limited to:

- Establishment of seven (7) Priority Work Areas (PWAs) including:
  - Multi-Regional Clinical Trials (MRCT) + Good Clinical Practices (GCP) Inspection;
  - Good Registration Management (GRM);
  - Pharmacovigilance;
  - Global Supply Chain Integrity;
  - Biotherapeutics;
  - Advanced Therapies; and,
  - Medical Devices;

- Implementation of a PWA Roadmap in all seven (7) PWAs to define the key issue and its importance, identify gaps in capacity, prioritize needs, develop a strategic program to close those gaps, and evaluate progress along the way;

- Establishment of 24 pilot and formal APEC Training Centers of Excellence for Regulatory Science (CoEs) at 16 host institutions across nine (9) APEC economies in all seven (7) PWAs to build skilled human capacity, promote dialogue with a view towards sharing understanding in science and best practices, achieve a model of sustainable operation, and avoid duplication of efforts;

- Development and maintenance of a Core Curriculum in all seven (7) PWAs containing the required elements based on relevant international standards and guidelines from the Roadmap that are needed in order to meet the training objectives of the CoEs;

- Establishment and monitoring of eleven (11) key performance indicators (KPIs) (*see original paper*) to measure and visualize progress towards achieving regulatory convergence for pharmaceutical products over the last decade and on an annual basis, including:
  - Number of economies engaging in information sharing;
  - Number of economies establishing confidentiality commitments;
  - Number of economies accepting PIC/S Good Manufacturing Practices (GMP) certificates to reduce the inspection burden;
  - Number of economies establishing Mutual Recognition Agreements (MRAs);
  - Number of economies minimizing required Certificates of Pharmaceutical Product (CPPs);
  - Number of economies allowing multiple sites in a single license;
  - Number of economies utilizing reliance practices in the regulatory evaluation;
  - Number of economies utilizing reliance practices to waive secondary quality control testing;

  - Number of economies in the International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH);
  - Number of economies in the International Pharmaceutical Regulators Programme (IPRP);
  - Number of economies in the Pharmaceutical Inspection Co-operation Scheme (PIC/S); and,

- Establishment and monitoring of eight (8) key performance indicators (KPIs) to measure progress towards achieving regulatory convergence for medical devices over the last decade and on an annual basis, including:
  - Number of economies in the International Medical Device Regulators Forum (IMDRF);
  - Number of economies in the Asian Harmonization Working Party (AHWP);
  - Number of economies in the APEC RHSC;
  - Number of economies accepting IMDRF Medical Device Single Audit Program reports;
  - Number of economies establishing MRAs;
  - Number of economies implementing IMDRF/GHTF premarket documents;
  - Number of economies implementing IMDRF/GHTF postmarket documents; and,
  - Number of economies implementing IMDRF/GHTF quality documents.

In August 2019 in Puerto Varas, Chile, the LSIF with support from the APEC Harmonization Center (AHC) organized the *2nd LSIF Policy Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence*. The Policy Dialogue convened the leaders of pharmaceutical and medical device regulatory authorities and representatives from industry and academia to reflect on a decade of progress towards regulatory convergence in APEC and to envision the next iteration of a strategy for achieving regional regulatory convergence of medical product approval procedures by 2030.

2. Purpose

The purpose of this document is to outline a new strategic framework to 2030—a structured method the RHSC will use to define how it supports the key objectives of its stakeholders including regulatory authorities, industry, academia, and scientific organizations. While this strategic framework will establish an updated vision, mission, and set of goals for the RHSC, it will more importantly describe how the RHSC will achieve these core elements, and do so in support of the broader goals of access to medical products, improved public health, and economic development.

The intended audience for this document includes members of the APEC LSIF and APEC LSIF RHSC, including representatives from government, medical product researchers and manufacturers, academia, and scientific organizations; APEC Health Ministers, Trade Ministers, and other Senior Officials; and patients, caregivers, and other end-users of regulated medical products.

3. Strategic Framework

3.1 Vision 2030

Our vision is to accelerate regulatory convergence for medical products in the APEC region as much as possible by 2030 in order to protect people's safety, make life-saving products available, save public resources, attract investment, mitigate corruption, and improve global standing in every APEC economy.

3.2 Mission

Our mission is to facilitate regulatory cooperation among medical product regulatory authorities, build human capacity in regulatory science among medical product regulatory staff, and promote political will for convergence and reliance among regulatory policymakers in APEC.

3.3 Values

Our values describe the individual and organizational behaviors that will enable the RHSC to achieve the mission and live the vision, to accelerate regulatory convergence and reliance.

- Clarity of the course ahead – we value clear goals and strategies, and the practice of horizon scanning to inform decision makers about possible future opportunities and threats.
- Centrality of the community – we value patients, caregivers, and other end-users of the medical products regulated in our economies.
- Calibration by outcomes & indicators – we value measurement of progress and performance, and its importance for communicating the 'why' and 'how' of regulatory convergence.
- Capacity building with strategy & sustainability – we value frontline regulatory staff, and the importance of enabling them long-term to obtain, improve, and retain skills and knowledge.
- Culture of collaboration – we value the opportunity to work together across teams, sectors, and economies toward common goals, and to provide every member with equal opportunity to lead.
- Connection between global, regional & local levels – we value coordination between stakeholders of global and regional initiatives and the member regulatory authorities and welcome their participation.
- Communication with politicians, patients & public – we value dialogue on regulatory convergence among the highest levels of government to the end-users of medical products.
- Commitment to improve – we value the constant pursuit of regulatory convergence, that it is never fully achieved or complete as new science drives novel products and updated regulations.

3.4 Definitions

- **Regulatory convergence** represents a voluntary process whereby the regulatory requirements across economies become more aligned (or more similar) over time as a result of the gradual adoption of harmonized international guidances and standards, and internationally recognized scientific principles, practices, and procedures. It does not seek to establish new or change existing legal frameworks, laws, or regulations. It does not require regulators to be subject to any outside authority or prevent regulatory authorities from protecting and promoting public health. It does not

have a specific endpoint; regulatory convergence is never "complete" or "achieved" as new products are developed, new standards are established, and new regulatory staff begin careers.

- **Regulatory reliance** is the act whereby the regulatory authority in one jurisdiction may take into account and give significant weight to – i.e., totally or partially rely upon – evaluations performed by another regulatory authority or trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others.

3.5 Guiding Principles

- RHSC will adopt a strategic, coordinated approach to regulatory convergence and reliance, and does not seek to develop new guidances or standards.

- While regulatory convergence by definition does not seek to establish new or change existing legal frameworks, laws, or regulations, RHSC may serve as a resource to APEC economies which have decided to establish or change these in pursuit of regulatory convergence and harmonization.

- Participation is voluntary and open to all APEC economies, and decisions are consensus-based.

- RHSC will work to constantly innovate and incubate new ideas to accelerate regulatory convergence building on past successes such as the APEC Training Centers of Excellence for Regulatory Science.

3.6 Goals, Strategies & Tactics

3.6.1 Goal: Facilitate regulatory cooperation among medical product regulatory authorities

A. Strategy: Build neutral platforms for cohesion and alignment
- **Action:** Convene meetings of the RHSC twice per year at the First and Third Senior Officials Meetings and provide space for side-meetings, workshops, and networking
- **Action:** Maintain Priority Work Areas (PWAs) with active PWA Champions[1], and Co-Champions, and PWA Steering Committees to help prioritize specific objectives, organize activities, and create communities
- **Action:** Create virtual spaces for regulatory cooperation through the RHSC website and email distribution lists which are updated at least twice per year

B. Strategy: Build tools for regulatory information-sharing and work-sharing
- **Action:** Provide and, if needed, assist in the development of template agreements and guidelines for information-sharing, work-sharing, memoranda of cooperation, confidentiality commitments, among others
- **Action:** Explore the feasibility of developing a technical platform to facilitate information-sharing and work-sharing between APEC regulatory authorities at scale

C. Strategy: Promote regulatory convergence and reliance and its tools
- **Action:** Organize regular workshops to explain and support the use of instruments of reliance including but not limited to sharing Good Manufacturing Practices (GMP) certificates; minimizing Certificates of Pharmaceutical Product (CPP) requirements; establishing Memoranda of Cooperation (MoC), Confidentiality Commitments, and Mutual Recognition Agreements (MRAs); and joining the Medical Device Single Audit Program (MDSAP); among others
- **Action:** Support participation in regulatory harmonization initiatives including but not limited to the International Council on Harmonisation (ICH), International Pharmaceutical Regulators Programme (IPRP), International Medical Device Regulators Forum (IMDRF), and Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), among others
- **Action:** Explore the feasibility of developing consensus-driven joint APEC commitments and bilateral or multilateral reliance agreements

[1] An RHSC member that leads the organization of activities to promote convergence within a PWA and serves as (1) the primary author of a PWA roadmap, (2) lead advisor to all CoEs within a PWA, and (3) chair of the PWA CoE Steering Committee.

3.6.2 Goal: Build human capacity in regulatory science among medical product regulatory staff

A. Strategy: Strengthen and scale APEC Training Centers of Excellence for Regulatory Science
- **Action:** Support the Center of Excellence Coalition to promote training activities, nominate participants to attend training activities, and encourage partnerships and collaboration between Centers of Excellence
- **Action:** Encourage consistent, long-term, and peer-to-peer training and the development of peer networks for participants in person and virtually following Center of Excellence training programs
- **Action:** Organize *ad-hoc* virtual and in-person workshops for Center of Excellence faculty to exchange information on topics such as innovative training methods
- **Action:** Enable more regulatory staff from more APEC economies to participate in Center of Excellence training programs by, for example, maintaining a comprehensive database of programs for the upcoming year and sharing information beyond APEC
- **Action:** Measure the short- and long-term learning outcomes of Center of Excellence programs with both quantitative and qualitative indicators

B. Strategy: Maintain strategic roadmaps and core curricula to guide programming
- **Action:** Review roadmaps every 5 years at a minimum, and core curricula every 2 years at a minimum

3.6.3 Goal: Promote political will for convergence and reliance among regulatory policymakers

A. Strategy: Explore new ways to measure regulatory convergence and its impacts
- **Action:** Continue measuring progress towards regulatory convergence with proxy indicators including but not limited to the number of APEC economies participating in regulatory harmonization initiatives, sharing GMP certificates, etc.
- **Action:** Analyze the macroeconomic case for and cost of inaction on regulatory convergence and reliance, and promote this information in regional and global fora

B. Strategy: Elevate the case for regulatory convergence and reliance, including at the highest political levels
- **Action:** Issue an annual letter from the RHSC Co-Chairs to the heads of regulatory authorities in APEC economies informing them of progress to date, outlining upcoming plans, and inviting them to participate in RHSC meetings
- **Action:** Organize policy dialogues to discuss regulatory convergence and reliance with a wider scope of APEC stakeholders, including regulatory policymakers, legislators and parliamentarians, patient organizations, and senior trade and health officials
- **Action:** Secure continued high-level political support for RHSC in annual statements from APEC Health Ministers, Trade Ministers, and Senior Officials, where applicable
- **Action:** Position APEC economies as champions of regulatory convergence and share progress with non-APEC economies

C. Strategy: Support policymakers seeking to establish or change legal frameworks, laws, or regulations
- **Action:** Organize policy dialogues to discuss regulatory convergence and reliance with a wider scope of APEC stakeholders, including regulatory policymakers, legislators and parliamentarians, patient organizations, and senior trade and health officials
- **Action**: Supply policymakers with guiding principles on decision-making towards the establishment or change of legal frameworks, laws, or regulations, when needed

3.7 Indicators

Goal: Facilitate regulatory cooperation among medical product regulatory authorities in APEC

- Process indicator(s): Number of APEC economies participating in RHSC, PWAs, virtually
- Output indicator(s): Index scores to measure perceived effectiveness of RHSC
- Outcome indicator(s): Existing RHSC KPIs

Goal: Build human capacity in regulatory science among medical product regulatory staff in APEC

- Process indicator(s): Number of hosts, Centers, training programs, faculty/participants
- Output indicator(s): Aggregate participant feedback with before-after training program analysis
- Outcome indicator(s): Pre- and post-training assessment with standard scoring system

Goal: Promote political will for convergence and reliance among regulatory policymakers in APEC

- Process indicator(s): Number of and participation at policy dialogues
- Output indicator(s): Aggregate participant feedback with before-after policy dialogue analysis
- Outcome indicator(s): Revisions to existing domestic legal frameworks, laws, or regulations; time duration of review

3.8 Anticipated Impacts

In working to achieve regulatory convergence and reliance we believe the anticipated impacts include:

- **Protects people's safety:** when economies take advantage of testing, inspections, and reviews already done by high-performing regulators around the region, economies can efficiently ensure approved products are both effective and safe, and work together to identify and share safety issues in their collective population.

- **Makes products available & promotes access:** when economies leverage the assessment work already done by high-performing regulators on a particular life-saving product, economies can approve that product more quickly and ensure it is readily available on the market to those who need it.

- **Saves public resources:** when economies tap into the expertise and work of other high-performing regulators around the region, economies can avoid unnecessary duplication and limit wasteful spending so economies save precious public health resources for use elsewhere.

- **Attracts investment:** when economies shorten burdensome procedures and adopt best practices by trusting the processes of high-performing regulators, economies can reduce uncertainty and delays so that both local and international firms find it easier to do business in APEC economies, invest their capital, and create jobs.

- **Improves efficiency:** when economies avoid duplicate inspections and lengthy approval procedures, economies can reduce the time it takes to respond to an application

- **Improves global standing:** when economies share the load with other regulators and join international initiatives, economies show their willingness to cooperate and support best practices, which strengthen the global community and enable investment in APEC economies.