APEC Life Science Innovation Forum
Regulatory Harmonization Steering Committee Meeting

Meeting Outcomes

February 10 - 11, 2018
Singapore

Participants

Membership from Economies: Michelle Limoli (Co-Chair, USA), Toshiyoshi Tominaga (Co-Chair, Japan), He Li (Vice Chair, China), Chao-Yi Wang (Chinese Taipei), Hsien-Yi Lin (Chinese Taipei), Yi-Chu Lin (Chinese Taipei), Arianti Anaya (Indonesia), Wulan Anom Sari (Indonesia), Lupi Trilaksono (Indonesia), Fumihito Takanashi (Japan), Junko Sato (Japan), Yoko Aoi (Japan), Yoshimasa Yokoyama (Japan), Mario Alanis (Mexico), Ambrose Kwaramb (Papua New Guinea), Vali Karo (Papua New Guinea), Yang Zhimin (China), Xu Mingzhe (China), Engr. Cecile Matienzo (Philippines), Maylene Beltran (Philippines), Hyeonho Kim (Korea), Sanghyun Kim (Korea), Yoo-Kyoung Lee (Korea), Srinivasan Kellathur (Singapore), Mary Ann Slack (USA), Guo Weiwei (China), Youngju Choi (AHC/Korea), Sukyoung Soeng (AHC/Korea), Minyoung Lim (AHC/Korea), Mirinea Kim (AHC Secretariat/Korea)

Industry Coalition: Janet Trunzo (Advamed), Lila Feisee (BIO), Katherine Tsokas (J&J), Nicole Taylor Smith (J&J), Thean Soo Lo (J&J), Naoki Morooka (JIRA), Kazuharu Matsuoka (JPMA), Osamu Inagaki (JPMA), Shinji Hatakeyama (JPMA), Kum Cheun Wong (Novartis), Camille Jackson (PhRMA), Angela Yan (RDPAC), Jiwen Zhang (Regenerative Medicines CB), Sannie Chong (Roche), Finny Liu (Roche Singapore), Tricia Chean (Roche Singapore), Dinesh Khokal (Amgen), Nishith Desai (APACMed), Fredrik Nyberg (APACMed), Mei Ding (PhRMA, AbbVie), Paul Dearden (PhRMA, AbbVie), Ee San Pek (PhRMA, Bayer), Emmeline Cheong (PhRMA, Bayer), Marta Parmar (PhRMA, Biogen), Lindsey Tao (PhRMA, J&J), Vicky Han (PhRMA, J&J), Dorothee Grimald (PhRMA, MSD), Romi Singh (PhRMA, Pfizer), Jayani DeSilva (PhRMA, Takeda), Mi Young Park (PhRMA, Takeda), Ling Zhou (PhRMA, Sanofi), Woon May Li (Sanofi), Lindsay Tao (PhRMA, J&J)

Centers of Excellence (CoE) Coalition: Neo Cherng Yeu (Duke NUS), John Lim (Duke NUS), Silke Vogel (Duke NUS), Gong Chen (PKU), Sandy Zhang (PKU), Kennard Brown (UT HSC), Lahouari Belgharbi (COFEPRIS), Jared Auclair (NEU), David Luzzi (NEU), De-In Shaw (RAPS Taiwan Chapter), Suh-Chin Wu (RAPS Taiwan Chapter), Yu-Hua Huang (RAPS Taiwan Chapter), Katherine Bond (USP), John Giannone (USP), Phillip Nguyen (USP), Sherry Wang (USP)

Official Observer: Samvel Azatyan (WHO)

APEC: Johnny Lin (APEC Secretariat), Patricia Wu (APEC LSIF Advisor), Michael Schmitz (APEC LSIF Secretariat)

Secretariat Josephine Wong (Duke-NUS)

*** Please refer to relevant Priority Work Area (PWA) roadmaps and slides presented at the RHSC meeting as background to the following items.**

1 Welcome and Introductions

Mr Johnny Lin was welcomed as the new APEC secretariat and Ms Josephine Wong (Duke-NUS) as the new RHSC secretariat.

2 Review Membership Lists, PWA Leads and new Contact Lists

- A contact list has been created with the following categories: 1) RHSC Leadership & Coordination 2) RHSC Regulators 3) RHSC Industry Coalitions 4) CoE representatives 5) RHSC Affiliates (Official Observers and Invited Guests)
- The contact list was circulated and updated by the delegates.

➢ **ACTION ITEM**

- The updated contact list will be circulated by the RHSC secretariat after the meeting. Any proposed revisions should be sent to the RHSC Secretariat.

3 APEC Harmonization Center (AHC) Report (Slide deck 3)

- AHC is hosting a website for CoE activities, and a document repository for CoEs and RHSC expressed its gratitude to AHC for the CoE website.
- Based on the success of AHC's e-learning Center, suggestions were made to add more materials (e.g. Pre-CoE workshop programs) in efforts to expand the target audience of the website beyond APEC.

4 RHSC Representatives' Reports

- ICH & IPRF (Slide deck 4)
- IMDRF (Slide deck 4.3)
    - Philippines and Mexico will be the APEC representatives for 2018.
    - Mexico and Korea will be the APEC representatives for 2019. As Korea is a member of IMDRF, they offered their position to another APEC economy.

➢ **DECISIONS**

- Chinese Taipei was endorsed to represent APEC at the IMDRF meeting starting 2019, for a 2-year term.

➢ **ACTION ITEMS**

- Device Industry coalition to submit a proposal for greater engagement of APEC at IMDRF.
- RHSC members and affiliates are invited to comment on the Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices on the IMDRF website by April 2018.

5 Update on Training Activities

- WHO (Slide deck 5.1)
- ICH Training Subcommittee (Slide deck 5.2)

6 APEC Secretariat Report

- APEC requires a quorum of 14 economies at sub-fora meetings; to be confirmed by the APEC Secretariat if this applies to RHSC.
- A sunset clause (4 years) is required in all APEC Terms of Reference documents; to be submitted by end of this month for review by LSIF.
- Document submission for APEC SOM-1 meeting by 13 February 2018.
- RHSC update will be given at APEC SOM-1 Meeting on February 28, session 6.
- RHSC was reminded of APEC Nomenclature & Publication guidelines.
    - There should not be any mention of countries but economies instead
    - No country flags or national maps should be shown in presentations.
- A suggestion was given by RHSC members to have a RHSC slide template for all presentations to ensure consistency.

➢ **ACTION ITEMS**

- RHSC secretariat to send out APEC publication guidelines.
- All RHSC members to review SOM-1 documents and make changes to adhere to APEC publication guidelines. The modified documents should be submitted to the RHSC Secretariat within 1 week.

7 Proposed KPIs for Convergence by Professor John Lim (Slide deck 7)

- Presentation based on a paper co-authored by Sannie SF Chong, John CW Lim and Toshiyoshi Tominaga that was submitted to a peer-reviewed journal for publication.
- KPIs (key performance indicators) were proposed to measure APEC Convergence based upon four areas of best practices which can be prioritized for economies not yet a member of PIC/S or ICH.
- There has been progress made by the various APEC economies due to the RHSC activities and these KPIs offer an opportunity to showcase the progress.
- KPIs by themselves are not stand-alone indicators and regulators should use the results of this analysis for self-evaluation on the progress they have made and plan to make and to address the challenges and limitations faced.

➢ **ACTION ITEMS**

- AHC to work with RHSC co-chairs to develop a questionnaire to survey the current status of APEC economies with an update by SOM-3.
- AHC to circulate the preliminary results before SOM-3 in preparation for discussions at the August RHSC meeting.

8 New Roadmap Template (Slide deck 8)

➢ **ACTION ITEMS**

- New PWAs should use the new streamlined template.
- Existing PWAs may revise using the new template if desired.

9 Good Registration Management Roadmap (Chinese Taipei -TFDA and Japan – MHLW/PMDA)

Reference Documents: Roadmap to Promote Good Registration Management (GRM)

- PWA Update (Slide deck 9.1)
- CoE update: TFDA/RAPS (Slide deck 9.2)
- CoE update: COFEPRIS (Slide deck 9.3)
- PhRMA Presentation: Expedited/Facilitated Regulatory Pathways (Slide deck 9.4)

➢ **DECISIONS**

- If COFEPRIS wishes to organize a 2nd GRM pilot workshop in 2018, a Pilot application should be submitted as the initial step.
- A half-day workshop on Expedited/Facilitated Regulatory Pathways will be held on the margins of the next GRM workshop in September 2018.

➢ **ACTION ITEMS**

- PWA Champion to send core curriculum to RHSC Secretariat.
- TFDA/RAPS to work with PhRMA Coalition on logistical details of the half-day workshop on Expedited/Facilitated Regulatory Pathways

➢ **PWA ACTIVITIES IN 2018**

- CoE program: TFDA/RAPS Taiwan Chapter (Sep 2018)

10 Multi-regional Clinical Trials and Good Clinical Practices Inspection Roadmap (Japan – MHLW/PMDA and Thailand-TFDA)

Reference Document: Roadmap to Promote Multi Regional Clinical Trials and Good Clinical Practice Inspection (GCP Inspection)

- PWA Update (Slide deck 10.1)
  - Suggestions were made to include Medical Devices GCP in the curriculum
- CoE Update: PMDA (Slide deck 10.2)
- CoE Update: Singapore Duke/NUS
  - No CoE Program was conducted in 2017 and there are plans for a program in 2019
- CoE Update: Peking University (Slide deck 10.4)
- Pilot Program Update: The MRCT Center of Brigham & Women's Hospital & Harvard (Slide deck 10.5)
- PhRMA Coalition Presentation: Performance Indicator Proposal (Slide deck 10.6)
  - Option 1: Self-reporting of implementation of related harmonized guidelines by RHSC Regulatory Members
  - Option 2: Establishing a method to track the types of clinical trials/ protocols conducted in APEC economies and resulting product labeling attributes over time
    - Feedback from regulators was that this option would lead to a huge burden for regulators and industry to track the number of region specific studies
  - Option 3: Establishing a methodology to ensure multiple MRCT CoEs have coordinated approach of setting training agenda and reporting outcomes

➢ **DECISIONS**

With regards to the PhRMA Coalition's Performance Indicator Proposal:

- Option 1 was endorsed by RHSC for the MRCT/GCP Performance Indicators.
- Option 2 will not be adopted. Rather, the number of MRCTs (protocols) conducted pre- and post- training and other measures proposed by PWA Champion were endorsed by RHSC for the MRCT/GCP Performance Indicators.
- Option 3 issues will be addressed by a steering committee to be organized by each PWA, similar to the Supply Chain Integrity Steering Committee (see their Steering Committee charter for reference).

➢ **ACTION ITEMS**

- PWA Champion to update roadmap and send to RHSC Secretariat
- PWA Champion to send core curriculum to RHSC Secretariat
- Medical Device PWA Champions and MRCT/GCP PWA Champions to determine in which PWA Medical Device GCPs will be housed by SOM-3 2018.
- PhRMA Coalition to consider refining and re-propose Option 2 in their Performance Indicator Proposal.

➢ **PWA ACTIVITIES IN 2018**

- CoE programs: PMDA (Jan 2018), PKU (Sept 2018)
- Pilot CoE: Harvard BWH (Apr 2018)

11 Biotherapeutic Products Roadmap (Korea –MFDS)

Reference Document: APEC Biotherapeutic Products Roadmap: To reach a high level of regulatory convergence by 2020

- PWA Update (Slide deck 11.1)
- CoE Update: Northeastern University (Slide deck 11.2)
- Pilot Program Proposal: Duke NUS (Slide deck 11.3)

➢ **DECISIONS**

- Duke NUS Pilot CoE program was endorsed by RHSC.

➢ **ACTION ITEMS**

- PWA Champion to make the Biotherapeutic Products roadmap more concise and submit to the RHSC Secretariat for circulation.
- PWA Champion to send core curriculum to RHSC Secretariat.

➢ **PWA ACTIVITIES IN 2018**

- CoE program: NEU (June/Sept 2018)
- Pilot CoE: Duke NUS (Nov 2018)

12 Global Medical Product Quality and Supply Chain Integrity Roadmap (US –FDA)

Reference Document: Roadmap to Promote Global Medical Product Quality and Supply Chain Security

- PWA Update (Slide deck 12.1)
- CoE Update: University of Tennessee Health Sciences Center

- CoE Update: United States Pharmacopeia (Slide deck 12.3)
- Pre-CoE Workshop Update: AHC (Slide deck 12.4)

➢ **ACTION ITEMS**

- PWA Champion to provide details of contact person to RHSC Secretariat.
- PWA Champion to send core curriculum to RHSC Secretariat.

➢ **PWA ACTIVITIES IN 2018**

- CoE program: USP Regulators Roundtable (Feb 2018)
- Pre-CoE workshop: AHC (May 2018)

13 Advanced Therapies Roadmap Update (Singapore - HSA)

Reference Document: Roadmap to Promote Prospective Regulatory Convergence for Advanced Therapy Products

- PWA Update by Singapore HSA (Word document 13.1)
- Pilot Program Update by Duke NUS (Slide deck 13.2)
  - Suggestion to add GRM to the workshop
  - As different topics will be covered each year, online learning materials can be developed and made available for the different topics.
  - There was a suggestion to use gap knowledge analysis and to compare the results from IPRP needs analysis.
- Pilot Program Application Update by Northeastern University (Slide deck 13.3)
- Advanced Therapies Industries Coalition Update on Standards Coordinating Board (Slide deck 13.4)

➢ **DECISIONS**

- Northeastern University Pilot CoE program was endorsed by RHSC.

➢ **PWA ACTIVITIES IN 2018**

- Pilot CoE: Duke-NUS (July 2018), NEU (Fall 2018/Spring 2019)

14 Pharmacovigilance Roadmap (Korea – MFDS)

Reference Documents: Roadmap to Promote Pharmacovigilance and Medical Device Vigilance

- PWA Update (Slide deck 14.1)
- CoE Update: PMDA (Slide deck 14.2)
- CoE Update: KIDS (Slide deck 14.3)
  Presented by MFDS on behalf of KIDS
- Pilot Program Update by MDITAC (Slide deck 14.4)
  - Reported under Pharmacovigilance as Medical Device PWA was only formed at SOM-3 2017

➢ **ACTION ITEMS**

- PWA Champion to send core curriculum to RHSC Secretariat

➢ **PWA ACTIVITIES IN 2018**

- CoE programs: PMDA (Feb 2018), KIDS (Sept 2018)

15 Medical Device PWA Update (Korea – MFDS; Japan-MHLW/PMDA; US -FDA)

Reference Document: Roadmap to Promote Regulatory Convergence for Medical Device Regulatory Systems

- Indonesia proposed the following changes to the Medical Device roadmap:
  - Section IIa) Pre-market, bullet point 4: "For medium and low risk class products, use of a conformity assessment of the essential principles utilizing recognized international standards and the essential principles check sheets is recommended. Third-party certification bodies are recommended for implementation." to be changed to "Regulatory or third-party certification bodies are recommended for implementation."
  - Section IIb) QMS: "For reciprocal acceptance of audit reports, consider using the IMDRF MDSAP reports" to be changed to "For reciprocal acceptance of audit reports, consider using international standards reports such as IMDRF MDSAP"
- PWA Update (Slide deck 15)
  - Looking for interested parties to be subtopic champions who would define topic of interest and draft a roadmap for that subtopic.

➢ **DECISIONS**

- RHSC agrees with the proposed changes to the roadmap made by Indonesia. Medical Devices Roadmap will be endorsed intersessionally after the proposed changes are made.

➢ **ACTION ITEMS**

- Indonesia to amend the Medical Devices Roadmap according to the proposed changes and send the document to the Medical Devices PWA.

➢ **PWA ACTIVITIES IN 2018**

- Pilot CoE: AHC (Nov 2018)

16 Report from CoE Coalition and Discussion (Slide deck 16)

- An informal CoE coalition meeting was held to promote collaboration of CoEs across the different PWAs and to share best practices
- Some of the discussion points were in the areas of governance and Intellectual Property
- Governance: The discussion was around the responsibility of governance of the CoEs to oversee the number of CoEs and the alignment and evolution of the curriculum
  - Each PWA has the responsibility of ensuring consistency in the curriculum and evolution of the curriculum through a steering committee
  - However, it was noted that CoEs have the flexibility to develop their own program based upon the core curriculum
- Intellectual property:
  - Ownership of Intellectual Property for the programs developed by CoEs was discussed
  - Also a discussion on whether program materials should be publicly disseminated (which could lead to misinterpretation and be counterproductive to the goal of regulatory convergence) or disseminated only to participants.

➢ **DECISIONS**

- Each PWA Champion(s) should convene a PWA steering committee that would discuss issues raised such as: keeping the core curriculum current, coordination and consistency across CoEs, the ideal number of CoEs for the PWA, and other relevant topics. (See the Supply Chain Integrity Steering Committee Charter as a model.)

17 Review and Discuss New/Revised CoE Supporting Documents

- *CoE Operating Model and Guidelines*
- *How to conduct an APEC CoE Pilot Program*
  - AHC noted that when a pilot CoE is supported by AHC, that the AHC logo should be used on all promotional materials for the pilot.
- *CoE and Pilot CoE Items to include on the AHC website*

➢ **DECISIONS**

- All 3 CoE supporting documents were endorsed by RHSC
- Since AHC provides financial support as well as in-kind support, the *CoE Operating Model and Guidelines* was amended to reflect this.

➢ **ACTION ITEMS**

- AHC terms of reference to be circulated to all CoEs

18 Performance Indicators Presentation and Discussion (Slide deck 19)

- PhRMA Industry coalition proposal (Slide deck 19.3)

➢ **DECISIONS**

- Each PWA Champion (through their newly-created Steering Committees) should define PIs relevant to their work area..

➢ **ACTION ITEMS:**

- Further discussion on PIs will be held at the August RHSC meeting.

19 Review Plan for August 2018 Meeting

- 2018 SOM-3 will be held in Port Moresby, Papua New Guinea from 4 – 20 August and RHSC meetings are slated for the middle of this time period.
- Items to be discussed at SOM-3:
  - Strategic discussion and conclusion on PIs in RHSC activities
  - Encouraging greater engagement of all 21 APEC economies in RHSC
  - To review current PWAs for possible sunsetting or maintenance mode, and the potential for taking on new PWAs. Some suggestions on new PWAs include:
    - Electronic standards (such as eCTD, MedDRA, E2B, IDMP, etc) based upon ICH guidelines and best practices for industry and regulators. (US-FDA)
    - Pharmaceutical Quality based on ICH guidelines (PhRMA)
    - Digital Health (PhRMA)
    - Precision medicine, Real World Evidence and Big Data (BIO)
  - Promoting & publicity of RHSC activities.

20 Any other Business

- Publicity of RHSC
  - LSIF advisor is assisting in producing a press release on the RHSC meeting.
  - Suggestion was made for a publication on RHSC as an interim step to the final report that is due to the LSIF in 2020.

➢ **ACTION ITEMS**

- RHSC Secretariat researching the establishment of an RHSC website.