Regulations and Approvals Expert Working Group (RA-EWG)

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APAC Convention

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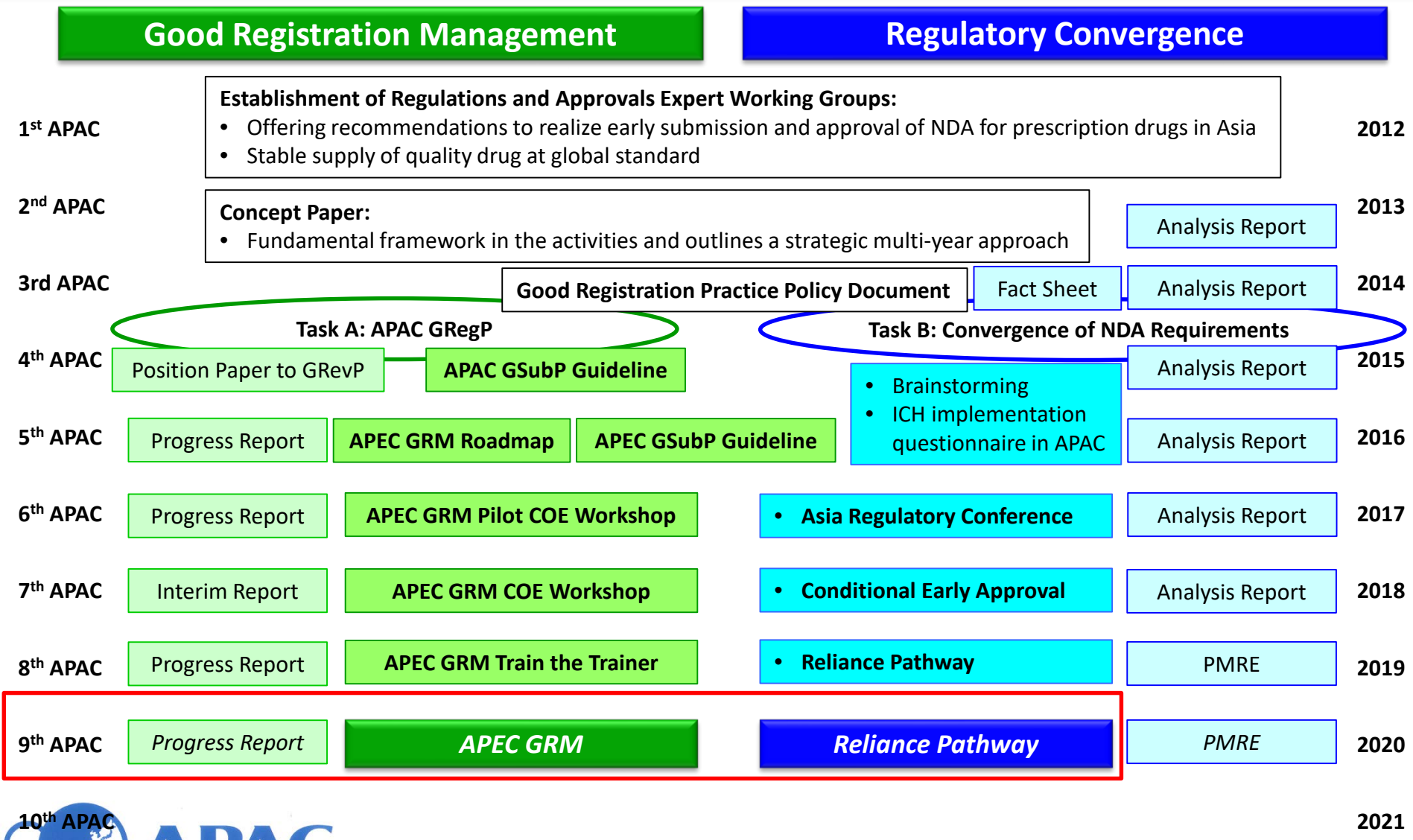
Regulations and Approvals Expert Working Group



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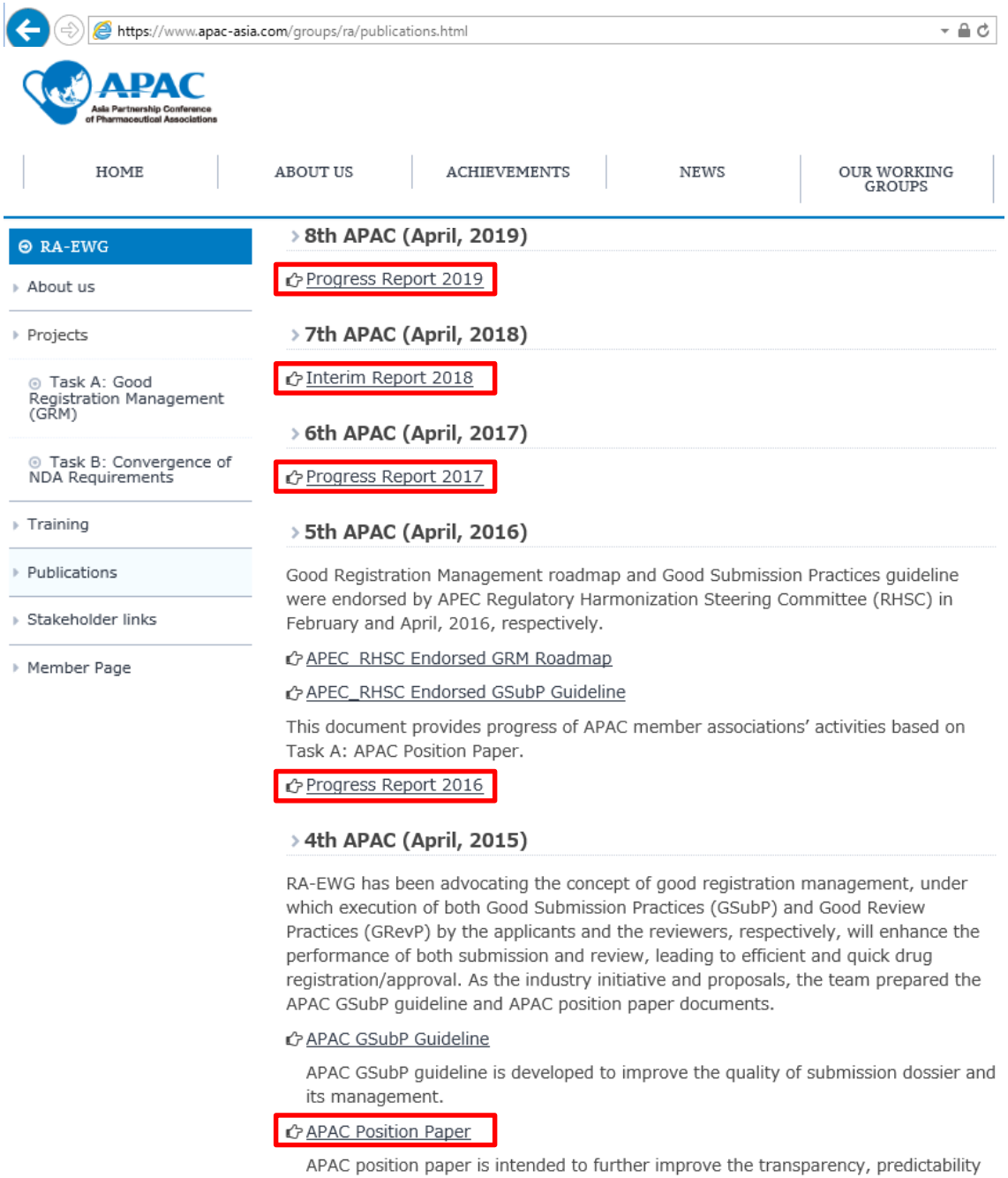
https://www.apac-asia.com/groups/ra/publications.html



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Progress Report 2020 (Cont'd)

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INTRODUCTION

Asia Partnership Conference of Pharmaceutical Associations (APAC) is a platform built by 12 Asian Pharmaceutical Industry's Associations to advocate industry proposals in order to expedite the launch of innovative medicines for the peoples in Asia. Regulations and Approvals Expert Working Group (RA-EWG), formed under APAC, has been working to support promotion of regulatory convergence in Asia.

APAC Position Paper (https://apac-asia.com/images/ra/pdf/pillar4/apac_position_paper.pdf), which was generated by RA-EWG and endorsed at the 4th APAC convention in April 2015, provides the five high level suggestions and proposals to the regulatory authorities from the viewpoint of industry. By facilitating close communication and collaboration between industry and the regulatory authorities based on APAC Position Paper, it is expected to improve regulatory environment and facilitate the regulatory convergence and work sharing of drug review in Asia.

APAC Position Paper covers 5 topics, (1) consultation, (2) transparency, (3) tracking system, (4) collaborative training, and (5) review report in English, which are selected as important area for refining existing drug registration process throughout the APAC region.

Topic #1: Structured framework of regulatory consultation system
Topic #2: Transparency to review policy, standards, draft regulations, guidelines and new initiative from regulatory authority
Topic #3: Review process tracking system
Topic #4: Collaborative training program
Topic #5: Generation of review report in English

APAC member associations have picked up topics of focus in their economy for further discussion with their authority (**Table**, *see next page*). This document provides progress of APAC member associations' activities based on focused topic(s) in APAC Position Paper.

Table Focused Topics by each association in their economy

China	**RDPAC** R&D-based Pharmaceutical Association in China	*Not selected yet**
Hong Kong	**HKAPI** The Hong Kong Association of the Pharmaceutical Industry	**#4****
India	**OPPI** Organization of Pharmaceutical Producers of India	*Not selected yet**
Indonesia	**IPMG** International Pharmaceutical Manufacturers Group	**#4**
Japan	**JPMA** Japan Pharmaceutical Manufacturers Association	**#5**
Korea	**KPBMA** Korea Pharmaceutical and Bio-Pharma Manufacturers Association	*None****
Korea	**KRPIA** Korean Research-based Pharmaceutical Industry Association	**#1**, #2****
Malaysia	**PhAMA** Pharmaceutical Association of Malaysia	**#3**, #4****
Philippines	**PHAP** The Pharmaceutical and Healthcare Association of the Philippines	**#2**, #3****
Singapore	**SAPI** Singapore Association of Pharmaceutical Industries	**#4****
Taiwan	**IRPMA** International Research-Based Pharmaceutical Manufacturers Association	**#4**
Thailand	**PReMA** The Pharmaceutical Research and Manufacturers Association	**#2, #3, #4**
Vietnam	**EUROCHAM** European Chamber of Commerce in Vietnam	*Not selected yet**

** No progress report provided*
*** Completed topic*
**** KPBMA's conclusion: No topic to be raised/tackled as an issue from the KPBMA viewpoints.*

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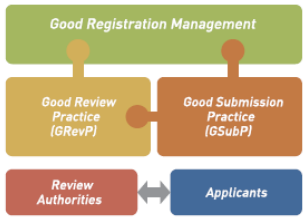
Good Registration Management

Goal of the GRM Roadmap



Purpose:
To promote GRevP and GSubP cooperatively

Long-term goals:
- Promote the concept of GRM
- Enhance mutual trust for regulatory convergence among APEC member economies by 2020

Good Review Practices (GRevP)
To help achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality in the content and management of reviews

Good Submission Practice (GSubP)
To enhance the quality and efficiency of the medical product registration process by improving the quality and management of submission

Specific Activities and Timeframes

2011-2012	2011-2016	2017-2019	2020~
Gap Analysis Survey for setting the foundation for Stepwise GRevP Implementation	Planned solutions to address Gap in GRM	Assessing impact of GRM ✓ Dissemination of GRM (continued) ✓ Assessing the impact of training and implementation of GRM using KPIs	Reaching the Goal for Implementing GRM

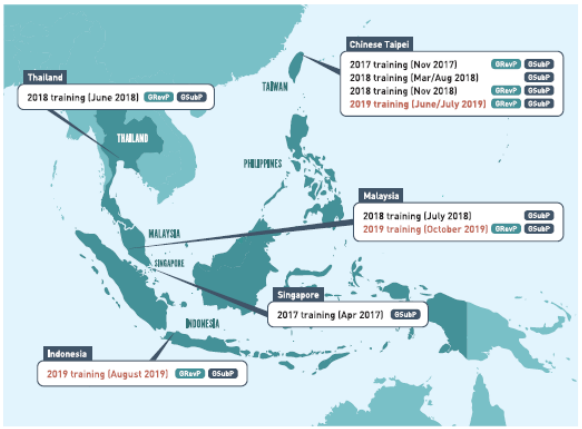
APEC GRM CoE Training Activities

August 2019-February 2020 **APEC TRAINING**

2019 APEC GRM CoE Workshop in Taipei
— September 17-19,2019
(TFDA/RAPS Taiwan Chapter)

2019 APEC GRM Pilot CoE Workshop in Bangkok
— October 26-28,2019 (Thai FDA)

GRM Local Training Activities



KPI Assessment of GRM Implementation is on-going
The result will be shared with all in the 10th APAC

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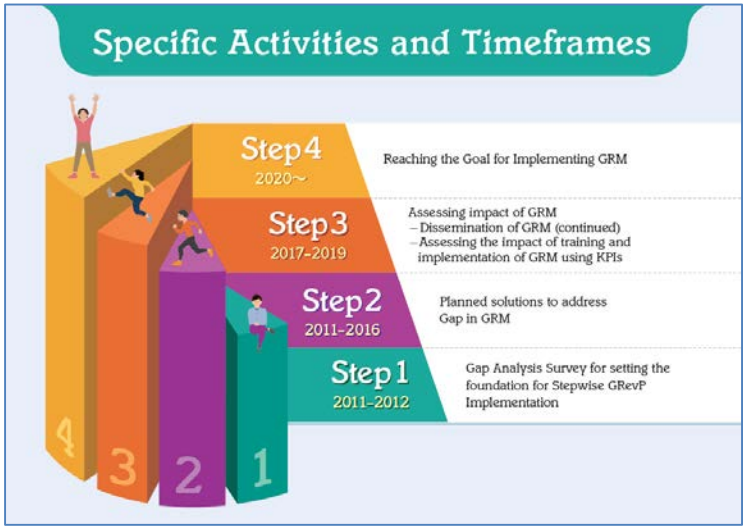
Good Registration Management (Cont'd)



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Summary for activities for reliance pathway on 2019

2020 April 2nd

RP discussion team

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Introduction

- Reliance pathway (RP) was started to be introduced in APAC countries.
- Being widespread use of RP is key for early access of drugs for patient and efficient resource for reviewers.
- Extracting and solving issues for RP in APAC countries is important to accelerate RP.
- We conducted discussion in RA-EWG, created questionnaires and collected challenging points on 2019.

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Summary of responses

- Received countries: Korea, Taiwan, Indonesia, Malaysia, Philippines and Japan
- Categories of RP:
  - Abbreviation/verification pathway like WHO Good review practice) : Indonesia, Malaysia, Philippines, Taiwan (Certificate of a Pharmaceutical Product)
  - Recognition related quality pathway like Memorandum of Understanding, GMP : Korea and Taiwan
  - Work sharing for NDA reviewing : Taiwan and Japan
- Advantage for HAs, Industries
  - Early access to Patients (i.e. efficient use of available resources)

Summary of responses (cont.)

- Challenging points
  - Information access (by all countries)
    - Non redacted/redacted assessment report in reference countries
    - Q&A documents
    - Verification if industries provide
    - Access CMC and safety review information
    - Direct communication between HAs
    - Translation in English
  - Existing differences in regulatory system and Legal obstacles (e.g. Labeling, specification etc.)
  - Need to maintain scientific capability and competence
    - For work sharing review
  - Resources,

Current discussion and next actions

1. Current challenging points for RP
   - Issues of information access from reference countries.
   - No clear process among Heath Authorities

2. Next actions (activates in 2020)
   - Detail discussion within 2-3 countries
   - Guidance for information access/clear process in APAC.
   - Creation of long term plan for RP activities (e.g. for work sharing ,etc.,)

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Thank you very much!