Summary of RA-EWG activities in FY2017

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JPMA

April 10th 2018
7th APAC RA Session

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Asia Partnership Conference of Pharmaceutical Associations

RA-EWG activities in FY2017

1. Promotion of Good Registration Management
2. APAC Position Paper Interim Report
   - JPMA Interim Report
3. Analysis Report
4. Regulatory Convergence for New Regulations

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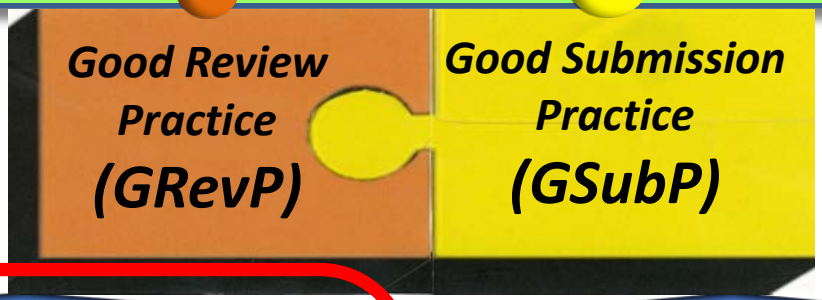
Promotion of Good Registration Management

Realize early access to new medicines for peoples in Asia

Enhance efficiency of NDA review

Good Registration Management



Make proposals to support facilitation of GRevP

- ***Further improvement in transparency, predictability and timeliness of review by facilitating communication***

APAC Position Paper

Improve quality of submission and its management

- ***Reduced number of critical deficiencies***
- ***Decrease of rejections***

APAC GSubP Guideline

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APAC Position Paper in 2015

#1: *Regulatory Consultation*

#2: *Review Policy, Standards, Draft Regulations, Guidelines and New Initiative*

#3: *Review Process and Status*

#4: *Collaborative Training Program and Workshop*

#5: *Generation of Review Report in English*

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APAC Position Paper Interim Report

- 2015 (4th APAC)
  - Position Paper for 5 topics →
- 2016 (5th APAC) ←
  - Progress Report 2016
- 2017 (6th APAC)
  - Progress Report 2017
- **2018 (7th APAC)**
  - **Interim Report (April 2015 – March 2018)**
    - Evaluation for 3-year progress

Each association;
- **Pick up focused topics**
- **Initiate dialogue with authority**

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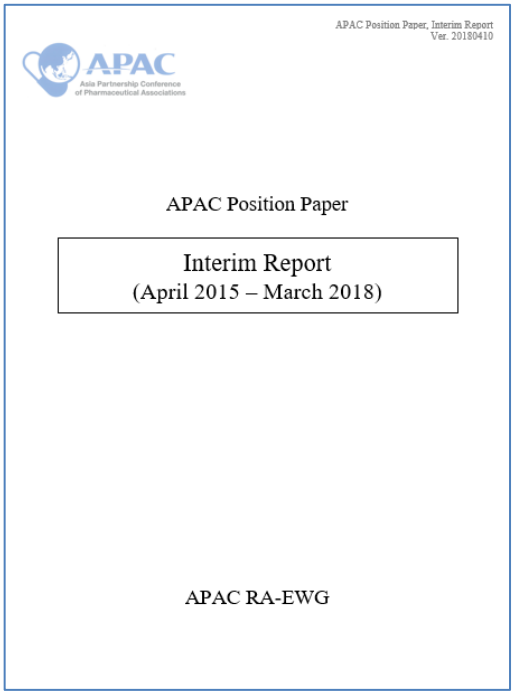
Interim Report (April 2015 – March 2018)

Table of Contents

- Focused Topic(s)
- Status as of April 2015
- Status as of March 2018
- Key progress
- Item to be solved
- Visual scale



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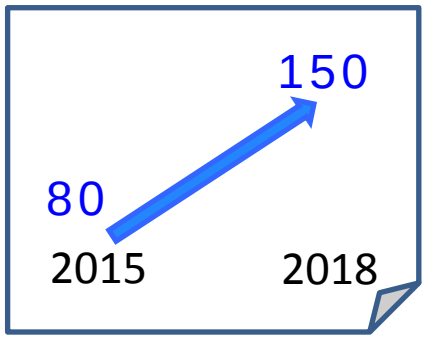
JPMA Interim Report

- **Focused Topic(s)**
  - Facilitating generation of review report in English
- **Status as of April 2015**
  - Around **80** review reports in English at PMDA website
- **Status as of March 2018**
  - Around **150** review reports in English at PMDA website



- **Key progress**
  - Twice questionnaires within JPMA
  - Multiple dialogues with PMDA to understand policy and target (1st Goal)
  - Continuous discussion with PMDA how to utilize review report in English
- **Item to be solved**
  - How to utilize review report in English
  - Actual achievement of utilization (2nd Goal).
- **Visual scale**

Usage of Review Reports in English

- NDA in Asia based on Approvals in Japan
  - Reference for Application for Approval in Asia

- Abbreviated review for innovative drug in Asia
  - Review reports from reference countries as documents for assessment

Analysis Report


Asia Partnership Conference of Pharmaceutical Associations (APAC)

Analysis Report

ver. 2018

Identification and Clarification of the Differences in Regulatory Requirements between Asian Economies

APAC Regulations and Approvals Expert Working Group

April 10, 2018
Tokyo, Japan

What regulations to be convergence…

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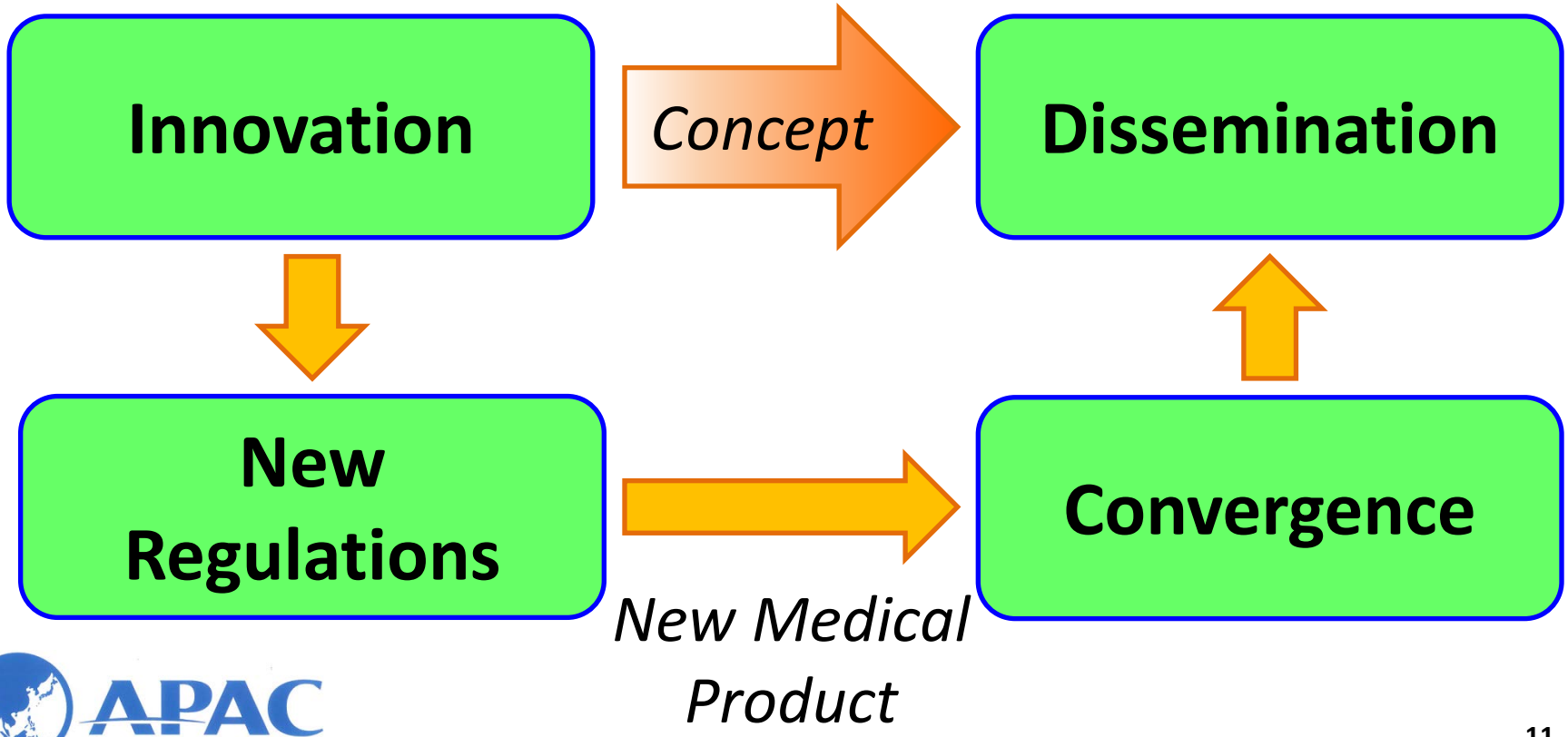
Analysis Report Member Associations

HKAPI	Hong Kong Association of the Pharmaceutical Industry
IPMG	International Pharmaceutical Manufacturers Group
IRPMA	International Research-Based Pharmaceutical Manufacturers Association
JPMA	Japan Pharmaceutical Manufacturers Association
KPBMA	Korea Pharmaceutical and Bio-pharma Manufacturers Association
KRPIA	Korean Research-based Pharmaceutical Industry Association
OPPI	Organization of Pharmaceutical Producers of India
PhAMA	Pharmaceutical Association of Malaysia
PHAP	Pharmaceutical and Healthcare Association of the Philippines
PhIRDA	Pharmaceutical Innovation and Research Development Association
PReMA	Pharmaceutical Research & Manufacturers Association
RDPAC	China Association of Enterprise with Foreign Investment R&D-based Pharmaceutical Association Committee
SAPI	Singapore Association of Pharmaceutical Industries
PG	Pharma Group (Vietnam)

Regulatory Convergence for New Regulations

7th APAC RA Session Panel Discussion

Conditional Early Approval



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RA session Consensus

Part-1; Good Registration Management (GRM)

- RA-EWG will continuously contribute the implementation of the APEC GRM CoE Workshop and the GRM/GSubP trainings in collaboration with GRM CoE.
- In FY2018, RA-EWG starts the examination of performance indicators for GRM/GSubP to assess the impact of the activities.

Part-2; Conditional Early Approval (CEA) System

- In the 7th APAC meeting, we have reached a consensus that CEA is an effective and efficient way to promote early access to highly necessary medicines for patients in Asia, and that multi-regional drug development and entry of medicines to different countries may face challenges without convergence of CEA approaches.
- RA-EWG will continue exploring the possibility of further convergence of early approval systems in Asia.

CoE: Center of Excellence, GSubP: Good Submission Practice

Thank you very much!!

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