Regulatory Agility during/after COVID-19

RA Session

10th APAC

April 13th 2021

APAC
Asia Partnership Conference of Pharmaceutical Associations

Agenda

<Time>	<Item>	<Speakers>
11:35 - 11:55 (20 min.)	Keynote Speech	Professor John Lim, Duke-NUS
11:55 - 12:35 (40 min.)	Panel Discussion	Panelists Jo-Feng Chi, Taiwan FDA Daisuke Koga, PMDA Rosilawati Ahmad, NPRA Sara Wang, RDPAC Facilitators Shinji Hatakeyama, APAC RA-EWG leader Vicky Han, APAC RA-EWG

APAC
Asia Partnership Conference of Pharmaceutical Associations

Keynote Speech

Regulatory Agility during/after COVID-19

RA Session

10th APAC

April 13th 2021

APAC
Asia Partnership Conference of Pharmaceutical Associations

Speaker

Professor John CW Lim

Executive Director

The Centre of Regulatory Excellence (CoRE) at the Duke-National University of Singapore Medical School (Duke-NUS)

Inaugural Chairman

The Consortium for Clinical Research & Innovation Singapore

Senior Advisor

Singapore's Ministry of Health (MOH)

Policy Core Lead

The SingHealth Duke-NUS Global Health Institute

Professor of Practice

Duke-NUS and the NUS Saw Swee Hock School of Public Health.

APAC
Asia Partnership Conference of Pharmaceutical Associations

Panel Discussion

Regulatory Agility during/after COVID-19

RA Session

10th APAC

April 13th 2021

APAC
Asia Partnership Conference of Pharmaceutical Associations

Panelists

Dr. Jo-Feng Chi

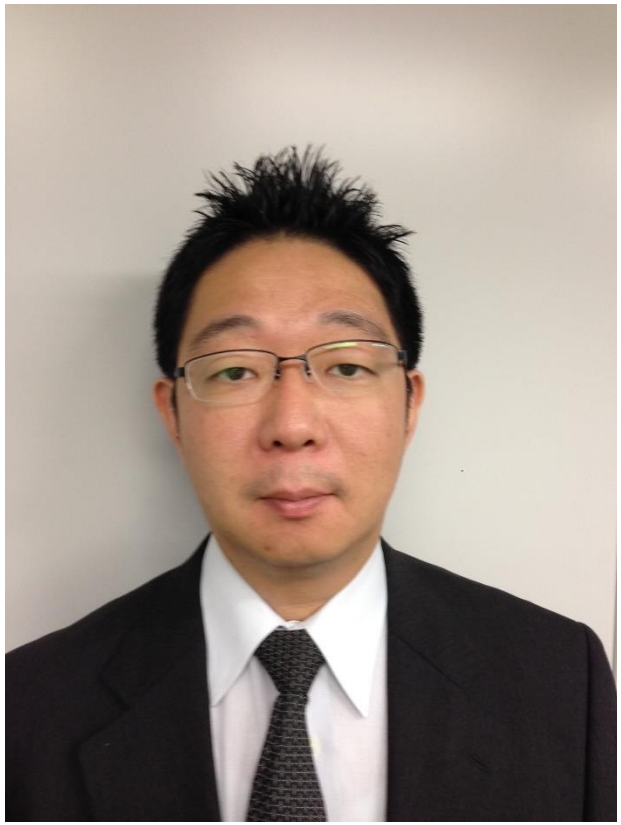
Researcher

Division of Medicinal Products

Taiwan Food and Drug Administration (TFDA)

APAC
Asia Partnership Conference of Pharmaceutical Associations

Panelists



Daisuke Koga

Division Director

Division of Planning and Management, and Division of Asia II

Office of International Programs

Pharmaceuticals and Medical Devices Agency (PMDA)

JAPAN

APAC
Asia Partnership Conference of Pharmaceutical Associations

Panelists

Rosilawati Binti Ahmad

Deputy Director

Product and Cosmetic Evaluation of National Pharmaceutical Regulatory Agency (NPRA)

Secretary

Drug Control Authority

Minister of Health Malaysia

APAC
Asia Partnership Conference of Pharmaceutical Associations

Panelists

Sara Wang

Senior Director

Science & Regulatory Affairs

RDPAC

R&D-based Pharmaceutical Association Committee

APAC
Asia Partnership Conference of Pharmaceutical Associations

Facilitators

Shinji Hatakeyama

APAC RA-EWG Leader

JPMA

Director

Asia Regulatory

Eisai Co., Ltd.

Vicky Han

APAC RA-EWG

Senior Director

Regulatory Policy Group Lead

Janssen Pharmaceuticals

APAC
Asia Partnership Conference of Pharmaceutical Associations

Discussion Points

Regulatory agility during/after COVID-19

1. Regulatory “New Normal” to address public health needs
2. Necessity and importance of reliance among regulatory authorities
3. Required contributions from industries
4. Sustainability of Regulatory “New Normal” after COVID19

Discussion Point 1

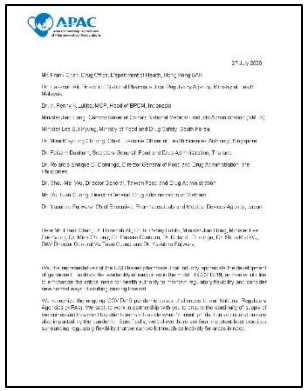
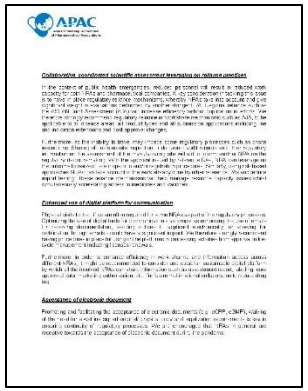
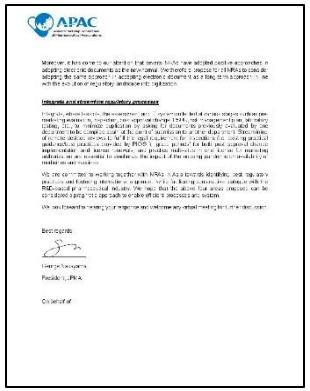
Regulatory “New Normal” to address public health needs

APAC letter related to COVID-19

27 July 2020

To National Regulatory Agencies in Asia

- Emphasizing Important Best Practices surrounding Regulatory Agility
  1. **Collaborative, coordinated scientific assessment leveraging on reliance practices**
  2. **Enhanced use of digital platform for communication**
  3. **Acceptance of electronic document**
  4. **Integrate and streamline regulatory processes**

APAC
Asia Partnership Conference of Pharmaceutical Associations

Discussion Point 2 & 3

Necessity and importance of reliance among regulatory authorities

Required contributions from industries

Cooperation between Taiwan and Japan

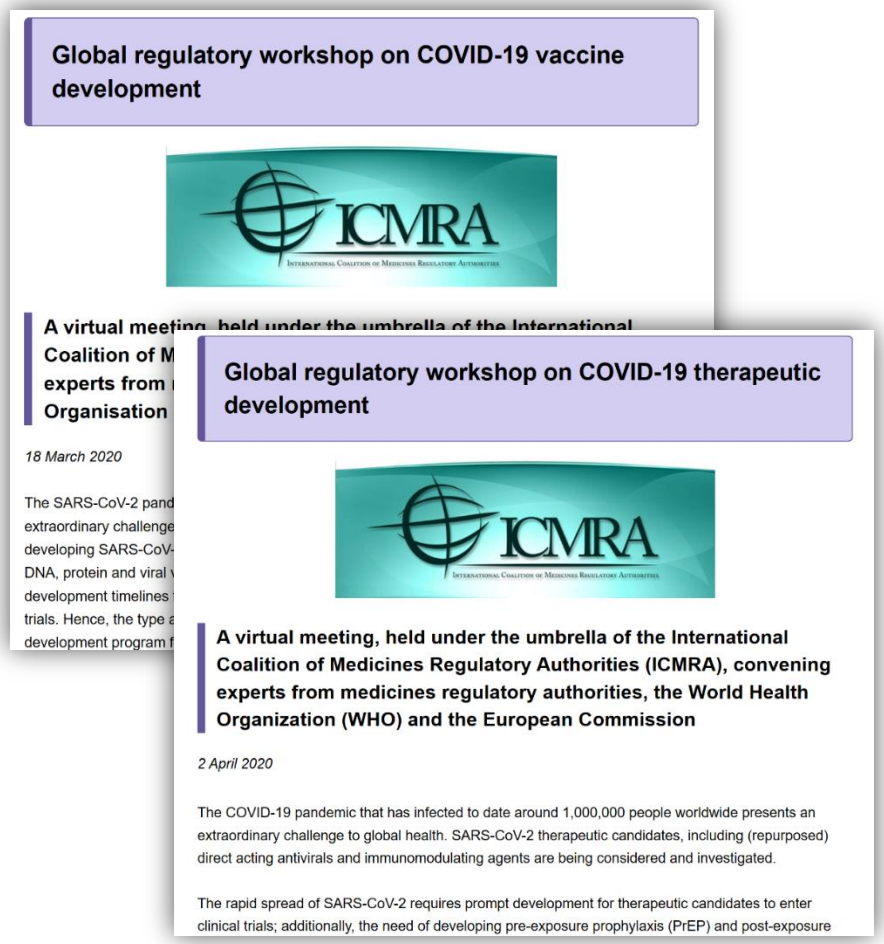
- **Establishment of the Framework of the Cooperation on the Medical Product Regulation** (Nov. 5th, 2013)
  - Share regulatory and industrial perspectives on pharmaceutical products and medical devices.
  - **Annual Meeting**: Joint Conference of Taiwan and Japan on Medical Products Regulation
  - **Regulatory working group**: New Drug, Generics, Medical Devices and Information Sharing.

New Drug Review Cooperation

- **Position Paper on New Drug Review Cooperation between Japan and Taiwan** (Oct. 2nd, 2019)
  - ✓ **exchange information regarding the review and registration** of New Drug Application (NDA), and **deepen understanding** on new drug review issues.
- **New Drug Review Scheme**
  - ✓ NDA from the Company will be reviewed through this review processes following regulations in Taiwan/Japan, respectively.
  - ✓ Under this Scheme, the English-version review report (unmasked) will be shared to the regulatory authority.
  - ✓ During the NDA review, PMDA and TFDA/CDE can exchange information and may have meetings to deepen understanding on review issues
  - Completed cases：2
  - Ongoing cases: 3

Discussion on COVID-19 product development at ICMRA

As of 9 April, 2021



Global regulatory workshop on COVID-19 vaccine development

ICMRA

A virtual meeting, held under the umbrella of the International Coalition of M… experts from … Organisation

18 March 2020

The SARS-CoV-2 pand… extraordinary challenge… developing SARS-CoV-… DNA, protein and viral … development timelines … trials. Hence, the type a… development program f…

Global regulatory workshop on COVID-19 therapeutic development

ICMRA

A virtual meeting, held under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA), convening experts from medicines regulatory authorities, the World Health Organization (WHO) and the European Commission

2 April 2020

The COVID-19 pandemic that has infected to date around 1,000,000 people worldwide presents an extraordinary challenge to global health. SARS-CoV-2 therapeutic candidates, including (repurposed) direct acting antivirals and immunomodulating agents are being considered and investigated.

The rapid spread of SARS-CoV-2 requires prompt development for therapeutic candidates to enter clinical trials; additionally, the need of developing pre-exposure prophylaxis (PrEP) and post-exposure

- COVID-19 Virus Variants Workshop (10 February, 2021)
- Pregnancy and Lactation Workshop (9, February 2021)
- Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #5 (25 January, 2021)
- Vaccine Safety Collaboration Workshop (13 January, 2021)
- Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #4 (13 October, 2020)
- Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #3 (22 July 2020)
- Global regulatory workshop on COVID-19 therapeutic development #2 (20 July, 2020)
- Global regulatory workshop on COVID-19 vaccine development #2 (22 June, 2020)
- Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #2 (19 May, 2020)
- Global regulatory workshop on COVID-19 Real-World Evidence and Observational studies #1 (6 April, 2020)
- Global regulatory workshop on COVID-19 therapeutic development #1 (2 April, 2020)
- Global regulatory workshop on COVID-19 vaccine development #1 (18 March, 2020)

Necessity and importance of reliance

- ICMRA plays a central role in the global cooperation to tackle a threat to global health and provides information which regulatory authorities can give significant weight for their decision-making.
- Reliance approach is expected to enhance the efficacy and efficiency of regulatory oversight, and it should be more prioritized in particular to achieve access to essential products in this emergency situation.

Contribution from industry

- Inputs from industry are beneficial for regulatory authorities to promote reliance approach.
- Participation of industries in regulatory procedures facilitated by reliance such as abridged pathways will contribute to foster trust between authorities.

Fast-Track Conditional Registration of Pharmaceutical Products During Disaster

Eligibility conditions

✓ Product is intended for serious or immediately life-threatening disease; AND
✓ Existing products unable in eradicating or preventing outbreaks; AND
✓ On-going Phase III clinical trial; AND
✓ Registered / have been given EUA in country of origin OR any DCA reference agencies OR WHO

Validity

✓ Conditional registration is valid for one (1) year and thereafter can be renewed two (2) times (with the possibility of 2 extensions of 1 year each).

Objectives

✓ Expedited access to pharmaceutical products for treatment or prevention during disasters without compromising aspects of QSE using a risk-based approach

Timeline

✓ Applications that fulfill the conditions will be given priority review status; 120 working days from the date of complete application received

Documents required

✓ Similar with normal pathway
✓Rolling submission is acceptable
✓Early clinical data (Phase I & II), with ongoing Phase III is acceptable
✓Any documents which are not available should be justified and subjected to the review of NPRA

ROSILAWATI AHMAD
Deputy Director, Centre of Product & Cosmetic Evaluation
National Pharmaceutical Regulatory Agency (NPRA) | Ministry of Health, Malaysia

ASEAN
Joint Assessment Coordinating Group (JACG)

Criteria for Product Selection

- ✓ Priority disease
- ✓ Products already approved by a reference NRA, or assessed through special regulatory pathways such as EU Article 58 or US-FDA tentative approval
- ✓ Products manufactured in a PIC/S-GMP compliant site

Objective

- ✓ Platform for cooperation/ to foster mutual trust and **reliance among AMS**
- ✓ Strengthen NRAs technical capacity
- ✓ To facilitate the review of priority medicines throughout ASEAN while respecting national-decision making processes
- ✓ To ensure regulatory work is conducted in a timely and efficient manner

Challenges & lesson learnt

01 Process Improvement

- Agreement on common templates for JA and timeline
- Establishment of Panel of Experts (POE) for technical assessment

02 Industry Engagement

- A need for further support using all possible means and mechanisms.
- The industry and other stakeholders have to see the potential benefits that the JA could provide in facilitation access to the priority medical products to ensure buy in

03 Short/Long Term Perspective

- Extending the list of priority medicines
- Formalize JA procedure as an additional registration pathway country level
- Harmonization of timelines
- Common list of reference agencies

ROSILAWATI AHMAD
Deputy Director, Centre of Product & Cosmetic Evaluation
National Pharmaceutical Regulatory Agency (NPRA) | Ministry of Health, Malaysia

NMPA in 2020

Fighting COVID-19

- Collaboration:
  - By early of Mar.2021, over 60 countries/regions authorize to use Chinese COVID-19 vaccines
- Regulatory:
  - Emergency approval channel for COVID-19 products: 4 vaccines, 54 test kits etc.
  - Guidelines to support COVID-19 products development
- Acceptance of e-CPP
- Remote inspection
- De-centralized clinical trial

Non-stop regulatory reform

- New regulations/guidelines
  - New Drug Registration Regulation (DRR) effected on July 1, 2020
  - Hundreds of DRR supporting guidelines released
- Process improvement
  - Four expedited pathways: Breakthrough, Conditional Approval, Priority Review and Special Review
  - Optimize registration process: Change sequential process to parallel
- Regulatory timeline improvement
  - NMPA target NDA timeline to 12 months similar as FDA/EMA/PMDA

Support and Ask from Industry

- Enhance collaboration among health authorities, industry and academy
- Industry continuous support for international harmonization
- Keep the continuity of the agility as “the new normal”: eCPP, remote inspection, DCT etc.
- Strengthen HAs cooperation to accelerate the innovative drug approval, especially for those Asia-indication
- Further carry on the reliance model for improving the regulatory efficiency & effectiveness among HAs

APAC
Asia Partnership Conference of Pharmaceutical Associations

Discussion Point 4

Sustainability of Regulatory "New Normal" after COVID19

APAC
Asia Partnership Conference of Pharmaceutical Associations

Consensus of RA session

<THEME>

- **Regulatory Agility during/after COVID-19**
  - Nevertheless global pandemic, necessity of medicine for various disease is unchanged.
  - "Expediting the launch of innovative medicine in Asia" is our sustained mission.
  - This time, we invited regulators from the health authorities in Asia, and facilitated panel discussion what kind of agile efforts are allocated for review of new medicine under the current situation.

<CONSENSUS>

- **Importance of "Regulatory new normal" based on regulatory agility by the health authority is well recognized, and APAC do our best efforts to support sustainable regulatory agility after COVID-19**

- **Cases shared from the health authorities at RA session**
  - Bilateral (Japan-Taiwan) and multilateral (ASEAN) Good Reliance Practice for facilitating efficient review of new medicines
  - Fast-Track Conditional Registration of Pharmaceutical Products During Disaster (Malaysia)
  - Participation in global collaborative efforts against COVID-19 pandemic by ICMRA（International Coalition of Medicines Regulatory Authorities）(Japan)