

Regulations and Approvals Session

Reliance Pathway for approval of innovative medicines in APAC

April 9, 2019

Chaired by

Dr. Junko Sato / PMDA

Prof. John Lim / Duke-NUS

BRIEF INTRODUCTION (5 MIN)

Agenda of Reliance pathway session

1	Brief Introduction	Chairs: Junko Sato (PMDA) John Lim (Duke-NUS)
2	Presentation <i>WHO's Approach to Promoting Reliance</i>	Speaker: Emer Cooke (WHO)
3	Panel Discussion <ul style="list-style-type: none">➤ <i>Short presentation by panelists</i>➤ <i>Discussion Point - 1</i><ul style="list-style-type: none">• <i>Consensus Building of Introducing Reliance Pathway</i>➤ <i>Discussion Point - 2</i><ul style="list-style-type: none">• <i>Infrastructure of Introducing Reliance Pathway</i>	Panelists: Noraisyah Mohd Sani (NPRA) Juliati (NAFDC) Lim Sok Bee (Duke-NUS) Sannie Chong (SAPI) Usanee Harnpramukkul (PReMA)
4	Summary & Future Direction	Chairs: Junko Sato (PMDA) John Lim (Duke-NUS)

Aim of Reliance pathway session

APAC Mission

“Expedite the launch of innovative medicines for the people in Asia”

Needs for early access of innovative drugs but resource of reviewers in each regulatory body is limited.



Reliance Pathway is one of solutions

Need to organize the Challenges to be introduced in the Asian region.

WHO's Approach to Promoting Reliance

PRESENTATION (20 MIN.)

PANEL DISCUSSION (40 MIN.)

Short Presentation by Panelists

i	Short presentations of actual reliance pathway from Thailand and Singapore <ul style="list-style-type: none">➤ <i>Thailand: Usanee Harnpramukul (PReMA)</i>➤ <i>Singapore: Sannie Chong (SAPI)</i>	Total 10 min (Slide)
ii	Challenging points to Indonesia and Malaysia in order to implement reliance pathway <ul style="list-style-type: none">➤ <i>Malaysia: Noraisyah Mohd Sani (NPRA)</i>➤ <i>Indonesia: Juliati (NAFDC)</i>	Total 6 min (Verbal)
iii	Benefits and Challenges of Reliance Pathways <ul style="list-style-type: none">➤ <i>Lim Sok Bee (Duke-NUS)</i>	5 min (Slide)

Discussion Point - 1

- Consensus Building of Introducing Reliance Pathway (RP)
e.g.)
 - How to permeate reliance pathway mindset
 - How to get understanding of each stakeholder to introduce RP
 - How to get agreement of RP introduction in the context of regulatory body's responsibility
 - Direction of getting consensus

Discussion Point - 2

- Infrastructure of Introducing Reliance Pathway
 - How to create legal framework between/among countries
 - Which countries will be contracted in RP
 - How to be contracted between/among countries?

SUMMARY & FUTURE DIRECTION (5 MIN.)

Future direction

2019 (8th APAC)

2020 (9th APAC)

2021 (10th APAC)

- The “**Guide for introducing RP**” in Asia are established based on the WHO guideline.

Step 1

- To reach consensus that the Reliance Pathway is a useful way of work sharing.

Step 2

Step 3

- Training in Asia
- Performance Indicator
 - ✓ How many bilateral/multilateral confidence-building
 - ✓ How many platform for training

Regulatory Convergence

~ Reliance Pathway for Approval of Innovative Medicines in APAC ~

- ◆ Encourage WHO's approach to the **Reliance Pathway** in Asia to facilitate efficient review and approval of innovative medicine based on bilateral/multilateral confidence-building by regulatory authorities
- ◆ Produce the following outcomes at the 9th APAC in 2020 based on the 3-years road map provided by the 8th APAC, as an effort to realize smooth introduction of the **Reliance Pathway** in Asia
 - 1) APAC guidance for encouraging WHO's approach to the **Reliance Pathway** in Asia
 - 2) Training platform to disseminate APAC guidance on **Reliance Pathway**