Summary of 12th Summit of Heads of Medicines Regulatory Agencies

Summit Symposium in Kyoto
27 October, 2017

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The week of 23 October

	23 Oct	24 Oct	25 Oct	26 Oct	27 Oct
AM	**Bilateral Meeting**	**Kyoto Summit**	**Kyoto Summit (Cont')**	**ICMRA (Cont')**	**Summit Symposium**
PM			**ICMRA**		

Today's contents

1. "Summit" and "ICMRA"
2. Outcome of the Summit
3. Major outcome of the bilateral meetings

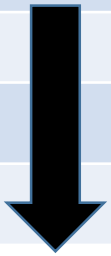
1. “Summit” and “ICMRA”

What is “Summit of Heads of Medicines Regulatory Agencies”?

- An annual forum where executives of medicines regulatory agencies discuss common issues.
- Started as FDA’s 100th anniversary in 2006, continued as the “Summit” thereafter.
- Closed Meeting with “Chatham House Rule”
  - Participants are free to use the information received, but the speakers are kept anonymous outside the meeting.
- Participation of 29 agencies.
  - For the 12th Summit, Japan invited Southeast Asian counties as ad hoc participants in addition to 22 members.

Summit of Heads of Medicines Regulatory Agencies
- Past Meetings -

Year	Country・Agency	Place	ICMRA
2006	US・FDA	Washington, D.C.	
2007	Ireland・IRB	Dublin	
2008	Singapore・HSA	Singapore	
2009	Canada・HC	Ottawa	
2010	England・MHRA	London	
2011	Australia・TGA	Sydney	
2012	Brazil・ANVISA	Manaus	Idea of “ICMRA” was conceived Established “ICMRA”
2013	Netherlands・MEB	Amsterdam	ICMRA face to face meeting in Washington, D.C., June in Amsterdam, December
2014	China・CFDA	Beijing	※ICMRA and Summit held back-to-back.
2015	Mexico・COFEPRIS	Mexico city	
2016	Switzerland・Swissmedic	Interlaken	
2017	Japan・MHLW/PMDA	Kyoto	



Comparison with International Coalition of Medicines Regulatory Authorities (ICMRA)

- Summit members and ICMRA members and associate members overlap.
- Summit and ICMRA face-to-face meetings are held back-to-back.
- ICMRA has more distinctly result-oriented
  - Mission : strategic coordination, advocacy and leadership
  - Strategic Projects: Supply Chain Integrity, Pharmacovigilance, Innovation, etc.
  - Transparency: Press Release, Statement, other work products on the ICMRA Website for transparency

Summit and ICMRA are closely linked

2. Outcome of Kyoto Summit

Outcome of Kyoto Summit

1. Innovation

2. International Cooperation

3. Merger of Summit and ICMRA

1. Innovation

- **Regulatory convergence on regenerative medicines.**
  - National regulations may need to evolve in order to better reflect the characteristics of the products.
  - International regulatory convergence at existing organizations (WHO, ICH, IPRF) is called for.

- **Use of Real World Data (RWD)**
  - Objective of the activities
  - How to translate RWD into RW Evidence for regulatory decision-making

    Collection, standardization, validation, verification, FAIR, etc.
  - Example: Use of registries

    Standardization, linkages, quality, right questions

    maintenance cost, etc.
  - Consider international symposium on RWD

2. International Cooperation

- **Fight against Antimicrobial Resistance (AMR)**
  - One Health approach
  - Role of national medicines regulatory authorities
    - Guidelines on clinical evaluation to stimulate pipeline and on appropriate use, promotion of research, monitoring, education, etc.
  - International cooperation
    - Regulatory convergence, regional efforts, tripartite (EMA, USFDA, PMDA) discussion
  - Role of WHO

- **Countermeasure against Substandard/Falsified medical products**

  - Role of national medicines regulatory authorities
    - Technology, database, inter-agency collaboration, multi-stakeholder engagement, cost, etc.
    - Track and Trace system
  - International cooperation
    - More convergence
  - Role of WHO
    - Capacity building
    - Surveillance, monitoring and alert

3. Major outcome of the bilateral meetings

Bilateral meetings (Major result)

9 meetings (with Japan) were held at the margin of the Summit

	Country / Region	Results
1	EC/EMA	• Basic agreement of mutual personnel exchange. • Progress on bilateral cooperation in the area of ATMP
2	Poland URPL	• Signatory ceremony of Confidentiality Arrangement (CA) for exchange of undisclosed information and expansion of MDSaP, progress on bilateral cooperation ※MDSaP: Medical Device Single Audit Program
3	Denmark DMA	• Basic Agreement of Confidential Arrangements and progress on bilateral cooperation
4	UK MHRA	• Selection of the individual area with mutual interest, and progress on mutual cooperation
5	Kingdom of Saudi Arabia SFDA	• Basic agreement of MOC and progress on bilateral cooperation

Bilateral meetings were also held with USFDA, Myanmar FDA, Korea MFDS and Indonesia NA-DFC.

Thank you

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