



Regional Update – ASEAN PPWG

by

Yuppadee JAVROONGRIT, Ph.D.

Co-Chair of ACCSQ/PPWG, ASEAN

Drug Control Division, ThaiFDA, Thailand

**The ICH-Global Cooperation Group Meeting
Hilton Fukuoka Sea Hawk Hotel, Fukuoka, JAPAN
09 November 2010**



Outcome

The 17th PPWG Meeting (22-23 July 2010, Yogyakarta, Indonesia)
“related to the ICH”



Outcome (1)

- **participants** ~310 from 9 countries (*Regulators + Industries*)
- **official opening** by Honourable Dra.Kustantinah MAppSc
(Head of the National Agency for Drug and Food Control of Indonesia)
- **back to back activities :**
 - **Technical Discussion on *ACTD-Quality and BA/BE Technical Guideline***
 - **the 7th Meeting of ASEAN Taskforce on MRA-BA/BE Studies**
 - **the 8th Meeting of the ASEAN Taskforce MRA - GMP Inspection**
 - **the 12th IWG Meeting**
 - **Head of Delegations (HOD) Meeting**



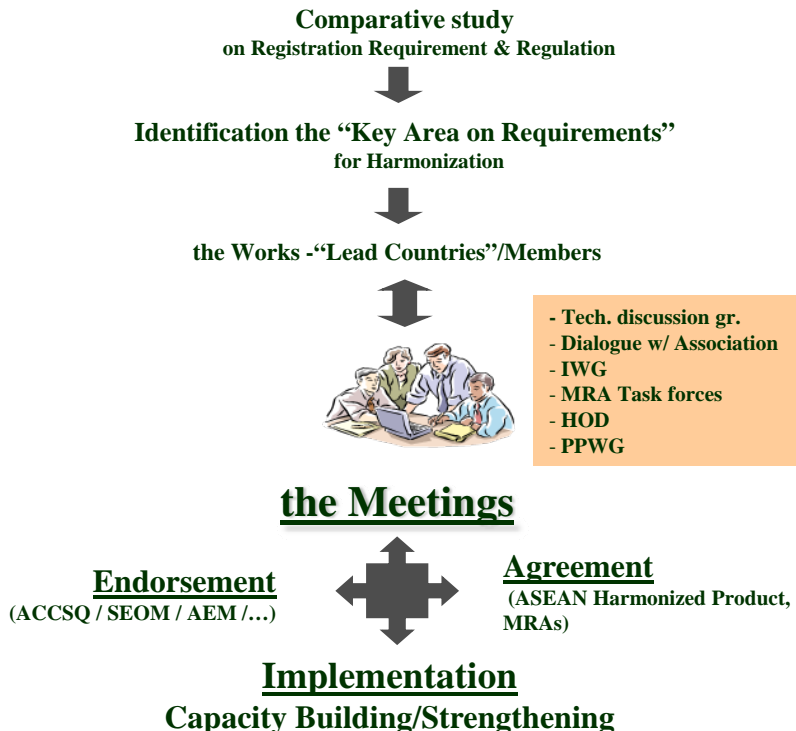
Outcome (2)

- **Important outcome :**

- proposal to study **the current *Safety & Efficacy Technical guidelines* of the ICH and other International guidelines**
- working on the draft *ASEAN Variation guideline*
- proposal to establish a *Technical Working Group (TWG)* for Biologics
- agreed on the list for the hosting of PPWG future Meetings;
 - 18th PPWG → Singapore
 - 19th PPWG → Thailand
 - 20th PPWG → Brunei Darussalam
 - 21th PPWG → Cambodia
 - 22nd PPWG → Indonesia.....



Working Scheme of the PPWG



Activities of PPWG

- (1) **Implementing ASEAN Harmonized products**
 - for new application
 - for existing Drug license (by 2012)
- (2) **Establishing GMP-MRA JSC**
- (3) **BA/BE MRA**
- (4) **Updating Tech.gls.**
- (5) **New areas of integration: Biological ,
Biotech., Biosimilar product**
- (6) **Facilitating the AEC**
- (7) **Coop.with international forum:
WHO, ICH, etc.**



Outcome (3)

ASEAN-PPWG and ICH-GCG (1)

- **GCG Update to the 17th PPWG** → by PPWG's Co-Chair

- **presented Topics :**

→ **GCG Meetings on 8 Jun.10**

→ **latest Update on GCG Meeting:**

- **Regulator Forum and RHI pre-meeting**
- **ICH update report & Topics**
- **MedDRA Management Board Special Session**
- **Finalization of RHI Profiles**
- **Webinars on *Step 2/Step 4* guidelines**
- **Quality IWG Training Workshop for Q8/Q9/Q10 guidelines**
- **AHC Activities**
- **Others Important topics**
 - *Training and Capacity building*
 - *Celebration of ICH 20th Anniversary*
 - *Evolution of the EU System for the Authorisation of Med.products*



Outcome (4)

ASEAN-PPWG and ICH-GCG (2)

- presented Topics (con't)

→ new EU contact points for ASEAN-Q5C Training WS

<peter.richardson@ema.europa.eu>, & <emer.cooke@ema.europa.eu>

→ the 3 project initiatives of Regulator Forum :

(ICH-Q7, ICH-E6, Good Review Practices)

→ Anticipating Future Training Needs, *related to ICH guidelines* :

- GCG encouraged submission of Training Needs, to be in advance
- by fill-in the Forms, and submit directly to the ICH Secretariat, or GCG Meeting



Outcome (5)

ASEAN-PPWG and ICH-GCG (3)

Recommendation to the 17th PPWG (1)

→ to note the outcome of the latest GCG Update (Tallinn)

→ to note, among all :

- outcome of RHI pre-meeting
- outcome of Regulatory Forum
- Celebration of ICH 20th Anniversary
- Quality IWG Training Workshop for Q8/Q9/Q10 guidelines
- evolution of the EU System for the Authorization of Med.products
- further details at ICH Website (www.ich.org)



Outcome (6)

ASEAN-PPWG and ICH-GCG (4)

Recommendation to the 17th PPWG (2)

- to note the progress of 3 ASEAN Training projects, endorsed by GCG, and *ASEAN focal-point* to coordinate further on Q5C Training project with new EU contact points
 - perter.richardson@ema.europa.eu
 - emer.cooke@ema.europa.eu

- to note the progress and highlights of *Regulator Forum*, and then consider participating, as contact person, to those initiative projects



Outcome (7)

ASEAN-PPWG and ICH-GCG (5)

Recommendation to the 17th PPWG (3)

- to consider participating the Webinar activities on Step2/Step4 guidelines, which could facilitate Guideline understanding and comments
- to note the *Training & Capacity Building* endorsed by GCG, and consider to submit the request for Future Training Needs, if any!



Outcome (8)

ASEAN-PPWG and ICH-GCG (6)

Outcome-the 17th PPWG

- noted the update of ICH-GCG
- agreed to the proposal from the PPWG Co-chair recommending Member States to participate in the Training activities



ASEAN Activities :- ASEAN & ICH-GCG

The Update

	Q8-9-10	Q5C
• Date	26-28 Jul.2010	-Mar.2011 / Q2-2011
• Contact point - ICH -ASEAN	-Mr.Jacque MORENAS -Mr.Muhammad L. IBRAHIM	- peter.richardson@ema.europa.eu - Emer.cooke@ema.europa.eu - Ms.Arpah ABAS(aarpah@bpfk.gov.my)
• Participant	- 27 regulators - 113 industries	Regulator & Industry
• Type	Regional Training	Regional Training
• Status	Done	<u>Request:</u> - re-confirm the EU-contact points - set-up timeline for “Training Date” - develop the “Training Agenda”



Recommendation to the GCG

- to note progress of the ASEAN- *17th PPWG Meeting*
- on the endorsed Q5C-Training projects of ASEAN
 - **To reconfirm EU contact-points**
<peter.richardson@ema.europa.eu>, & <emer.cooke@ema.europa.eu>
 - **To help set-up timeline for training : Mar.2011/ Q2-2011**



Thank You

