Regional Update – ASEAN PPWG

by

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Drug Control Division, ThaiFDA, Thailand

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

Yuppadee – 09Nov.10, Fukuoka, JP
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
    - 21st PPWG → Cambodia
    - 22nd PPWG → Indonesia..................
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.

Working Scheme of the PPWG

Comparative study on Registration Requirement & Regulation

Identification the “Key Area on Requirements” for Harmonization

the Works - “Lead Countries”/Members

Endorsement (ACCSQ/SEOM/AEM/…)

Agreement (ASEAN Harmonized Product, MRAs)

Implementation Capacity Building/ Strengthening

the Meetings

- Tech. discussion gr.
- Dialogue w/ Association
- IWG
- MRA Task forces
- HOD
- PPWG
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
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

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<th>Q5C</th>
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<td>26-28 Jul.2010</td>
<td>-Mar.2011 / Q2-2011</td>
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<tr>
<td><strong>Contact point</strong></td>
<td>- Mr. Jacque MORENAS</td>
<td>- <a href="mailto:peter.richardson@ema.europa.eu">peter.richardson@ema.europa.eu</a></td>
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<tr>
<td></td>
<td>- Mr. Muhammad L. IBRAHIM</td>
<td>- <a href="mailto:Emer.cooke@ema.europa.eu">Emer.cooke@ema.europa.eu</a></td>
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<td>- <a href="mailto:aarpah@bpfk.gov.my">Ms. Arpah ABAS</a>(<a href="mailto:aarpah@bpfk.gov.my">aarpah@bpfk.gov.my</a>)</td>
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<td><strong>Participant</strong></td>
<td>- 27 regulators</td>
<td>Regulator &amp; Industry</td>
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<td>- 113 industries</td>
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<td>- re-confirm the EU-contact points</td>
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<td>- set-up timeline for “Training Date”</td>
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<td>- develop the “Training Agenda”</td>
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- **27 regulators**
- **113 industries**

Yuppadee – 09Nov.10, Fukuoka, JP
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