Regional Update – ASEAN PPWG

by

Yuppadee JAVROONGRIT, Ph.D.
Co-Chair of ACCSQ/PPWG, ASEAN
Drug Control Division, FDA, Thailand

The ICH-Global Cooperation Group Meeting
Radisson SAS Hotel, Brussels, Belgium
08 May 2007
Outcome from The 12th PPWG Meeting

November 2006, Indonesia
Outcome (1)

- **participants** ~ 300 from 9 countries

- **back to back activities**
  - 2nd Meeting of ASEAN Taskforce on MRA-BA/BE Studies
  - Technical Discussion on Quality and Stability Q&A
  - WHO-ASEAN Vaccine Chapter Meeting
  - Dialogue with Industry
  - 7th IWG Meeting
  - 3rd Meeting of the ASEAN Taskforce MRA - GMP Inspection

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Outcome (2)

Progress on the Implementation Issues of ASEAN Harmonized Product

“ASEAN MRA for Pharmaceuticals”

(1) ASEAN MRA-BA/BE Studies
   → progressed & reached various Agreement
   → TOR was revised & adopted !
   → Action plan was developed & implementing

(2) ASEAN MRA-GMP Inspection
   → agreed on Report Format, Code of GMP, Inspection, ….
   → Sectoral MRA was drafted & consulting process now
   → Is expected to be ready for signing by the end of 2007

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Outcome (3)

Progress on the Implementation Issues of ASEAN Harmonized Product

**ACTD Quality & ASEAN Tech. gls.**

- ACTD Quality & ASEAN Stability gl. → adopted “Booklet on Q&A”
- ASEAN Analytical Validation gl. → requested a dev. of Q&A’s Booklet
- ASEAN Process Validation gl. → requested a dev. of Q&A’s Booklet
**Outcome (4)**

Progress on the Implementation Issues of ASEAN Harmonized Product

“Dialogue with ASEAN Industries”

(1) **The Industries**
   - APC (ASEAN Pharmaceutical Industry Club)
   - APRIA (ASEAN Pharmaceutical Research Industry Association)

(2) **Agreement**
   - advance submission of their proposals
   - direct dialogue with PPWG

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Outcome (5)

Progress on the Implementation Issues of ASEAN Harmonized Product

**ACTD Implementation**

- **ACTD format** ➔ Member countries are committed to ACTD format for submission of product registration

- **ICH-CTD format** ➔ Member countries are allowed to exercise flexibility in accepting the ICH-CTD format for NCEs & Biologics product

- **Boundary of Acceptance** ➔ refers to acceptance of Format, and does not include the Evaluation of the Dossiers
Outcome (6) ASEAN-PPWG and ICH-GCG (1)

- GCG Update to the PPWG ➔ by PPWG’s Co-Chair
- Topics

➔ GCG Meetings (Agenda/Venue/RHI participation)

➔ GCG Update
  • RHI pre-meeting rpt
  • Stability dev.
  • RHIs’ participating in EWGs
  • Query from Indian Regulatory Authority
  • Training & Capacity-building (+ ICH-GCG Training Opportunities and Harmonisation Events)
  • RHI Survey (+ RHI Global Questionnaire of ASEAN/PANDRH/GCC-DR/SADC-PHI, +Profile Table)

➔ ICH Update
  • Current Working Topics
  • Openness
  • Working Structure

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Recommendation to the 12th PPWG (1)

- to note the GCG Update, presented by Co-Chair

- to note the following matters, in particular :
  - other RHIs’ willingness to respond on Step 2 doc. of ICH
  - intention of Indian RA to join the GCG
  - GCG / ICH support to APEC’s requests (Speakers/Trainers)
  - ICH Current Working topics & its Openness
Recommendation to the 12\textsuperscript{th} PPWG (2)

- to submit response on WHO’s Stability guideline (National / Regional)

- on Training & Capacity-building
  - to participate in “ICH” & “other RHIs” Training/Events (‘attachment 1’)
  - to provide opportunity for “other RHIs” to participate!
  - consider to submit Requests to GCG for Speakers/Trainers
    - ICH-CTD
    - other ICH-guidelines, adopted by the PPWG

- on ASEAN ‘Draft’ Questionnaire (‘attachment 2’)
  - to review
  - and feedback to Co-Chair of PPWG by 30 January 2007

- consider the benefit of ICH Working Structure towards PPWG
Outcome (6)

ASEAN-PPWG and ICH-GCG (2)

- noted the latest development of GCG (briefed by Co-Chair of PPWG)
- agreed ….

(1) Participation of RHIs in Capacity Building
   ➔ can be considered on a case to case basis
   ➔ Member countries can decide whether to invite RHIs to participate in their national activities

(2) A Need to convey a Stability Storage Condition to WHO Headquarter
   ➔ common position of ASEAN is 30C/75%RH
   ➔ tasked INDONESIA to follow-up the matter with the WHO-HQ & Update PPWG

(3) ASEAN Draft Questionnaire to the GCG
   ➔ Member countries to submit their comments to Co-Chair by 30 Jan 07
   (Note: Up to now, no comments are submitted !)

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Outcome (7)

- agreed on the next Meeting
  - Date → Aug.07
  - Venue → Malaysia
Thank You