Regional Update – ASEAN PPWG

by
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The ICH-Global Cooperation Group Meeting
Yokohama Royal Park Hotel, Japan
30 October 2007
Outcome

The 13th PPWG Meeting
July 2007, Malaysia
**Outcome (1)**

- **participants** ~ 250 from 10 countries

- **back to back activities:**
  - HODs /Special Meeting
  - 3rd Meeting of ASEAN Taskforce on MRA-BA/BE Studies
  - Technical Discussion on:
    - Q&A on Analytical Validation gl
    - Q&A on Process Validation gl
    - Q&A on Stability study gl and ACTD-Q
  - 4th Meeting of the ASEAN Taskforce MRA - GMP Inspection
  - Dialogue “IWG & P’cal Industry”
  - 8th IWG Meeting
Outcome (2)

Handover of Chairmanship

Mdm. Eisah Abd. Rahman (Malaysia) \[\text{Chair}\]

Y.Bhg. Dato’ Che Modh Zin Che Awang (Malaysia)

with the same Co-Chair
Yuppadee JAVROONGRIT (Thailand)
Progress on the Implementation Issues of ASEAN Harmonized Product

“ASEAN MRA for Pharmaceuticals”

(1) ASEAN MRA-BA/BE Studies
   - harmonization of Comparator Product
     - Definition
     - Selection

(2) ASEAN MRA-GMP Inspection
   - completed Final Draft “MRA”
   - processing “National Consultation”
   - targeted to be endorsed in “the 14th PPWG meeting”
   - planned for the Signing in April 2008
Outcome (4)

Progress on the Implementation Issues of ASEAN Harmonized Product

ACTD Quality & ASEAN Tech. gls.

Q & A of:

- ACTD Quality (ver.2)
- ASEAN Analytical Validation gl.
- ASEAN Process Validation gl.(ver.2)
- ASEAN Stability Study gl.(ver.2)

→ finalized and endorsed” !!!
Outcome (5)

Progress on the Implementation Issues of ASEAN Harmonized Product

“ACTD Implementation (1)”

(1) ASEAN vs. ICH format

ICH format is allowed for “NCEs” & “Biological products”, and
- need the compliance with
  - ASEAN Tech. Requirement, including Quality gls
  - ACTD-Administrative
- must include Raw Data
- Numbering system should be accepted
Outcome (6)

Progress on the Implementation Issues of ASEAN Harmonized Product

“ACTD Implementation (2)”

(2) Implementation of the ACTD

→ by 1st Jan.09 for the Whole Region
→ referred to ACTD Format
  - includes parameter + component
  - content be based on ‘ACTR & ASEAN Tech. gls.’
→ apply for all ‘First /New submission’ of the dossier
Other Progresses of the PPWG

- **Stability storage condition in ASEAN**
  - followed-up with WHO on ASEAN Common position (zone IV b-30C/75%RH)
  - informed “an amended WHO’s QAS/06.179/Rev.1”

- “**Vaccine Chapter**”
  - completed of the need assessment on Capacity Building
  - to coordinate with WHO, further

- **Non-ASEAN citizen (work in ASEAN)**
  - allow to participate in ‘IWG-Industry Dialogues’
  - 2 per Country
  - to be nominated by National Head of Delegation
Outcome (8)

New Tasks of the PPWG

- revision of the IWG’s TOR
- ‘ASEAN Regulatory Science Training Accreditation Scheme’
- ‘Mechanism’ to involve Scientists & Experts in PPWG’s Scientific activities
- cooperation with WHO on Anti-counterfeit Drugs
- explore possible assistance on “Capacity Building” with the US
- New ‘Organizational Structure’ of PPWG & IWG
Outcome (9)

ASEAN-PPWG and ICH-GCG (1)

- GCG Update to the PPWG ➔ by PPWG’s Co-Chair
- presented Topics:
  ➔ GCG Meetings (Agenda/Venue/RHIs participation)
  ➔ GCG Update
    • RHI pre-meeting rpt
    • RHI update
    • Comment on Step 2-ICH Tech. gl.
    • Stability gl. development
    • RHI Survey update
    • Brainstorming on GCG’s Goal
    • Training Requests (procedure/template, 2 APEC’s requests)

  ➔ ICH Update
    • EWGs’ meeting in Brussels
Outcome (10)

ASEAN-PPWG and ICH-GCG (2)

- recommendation to PPWG (1):
  → to note the GCG Update, presented by Co-Chair
  → to note the following matters, in particular :
    • the Final ASEAN Global Questionnaire
    • RHI pre-meeting report
    • RHIs’ update
    • ICH Current Working topics
  → on Training & Capacity-building
    • to note APEC’s requests for Training
    • consider to submit Requests to GCG for Speakers/Trainers

Send Requests to PPWG’s Co-Chair by 15 Sep. 07 !!!
Outcome (11)

ASEAN-PPWG and ICH-GCG (3)

- recommendation to PPWG (2):

  → on Table on Regional Guideline Works

  • relevant Lead Country to review/complete the Table (attached)

  *Feedback to PPWG’s Co-Chair by 15 Sep.07***
Outcome (12)

- PPWG:
  - expressed Appreciation to the Co-Chair for her excellent efforts
  - however, reiterated its Decision (at the 8th Meeting), that

...Participation of PPWG’s Rep. in GCG activities...

  ➔ as an Observer
Outcome (13)

- **agreed** on the 14th Meeting
  - Date → Jan. / Feb. 2008
  - Venue → LaoPDR

- **agreed** on the 15th Meeting
  - Date → Jul. / Aug. 2008
  - Venue → Brunei Darussalam
Thank You