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
Portland Marriott Downtown Waterfront Hotel, Oregon, USA
03 June 2008
Outcome
The 14th PPWG Meeting
Feb.08, LaoPDR
Outcome (1)

• **participants** ~ 250 from 9 countries

• **official opening** by H.E. Khamhoung Heuangvongsy,  
  (Vice Minister of Health, MOH of Lao PDR)

• **back to back activities:**
  - Head of Delegations (HOD) Meeting
  - 4th Meeting of ASEAN Taskforce on MRA-BA/BE Studies
  - Technical Discussion on :-
    - Q&A on ACTD-Quality
    - Q&A on ASEAN Technical guidelines
  - 5th Meeting of the ASEAN Taskforce MRA - GMP Inspection
  - Dialogue “IWG & P’cal Industry”
  - 9th IWG Meeting
Progress on the Implementation Issues of ASEAN Harmonized Product

“ASEAN MRA for Pharmaceuticals”

(1) ASEAN MRA-BA/BE Studies
   → Minimum Requirement for Analytical Laboratory Std.
   → Format of BE Study Report

(2) ASEAN MRA-GMP Inspection
   → amendment of the Final Draft “Sectoral MRA”
   → working on Designation to Joint Sectoral Committee (JSC)
   → plan for the Signing after the finalization of the “Sectoral MRA”
**Outcome (3)**

Progress on the Implementation Issues of ASEAN Harmonized Product

“**The Implementation Working Group-IWG**”

(1) revised TOR

- composition: *Chair, Co-chair, 4 Regulators/country, APC, APRIA, ASEC’s Rep., Observers*
- the Meeting – *open to both Regulators and Industries*
- term – *3 yrs.*

(2) Term Extension

- adoption of the revised TOR
- extension of IWG for 1 more term
- with same Chair (Sg) and Co-chair (Id)

**Note:**
- APC = ASEAN Pharmaceutical Club (domestic industry)
- APRIA = ASEAN Pharmaceutical Research Industry Association (multinational industry)
Outcome (4)

Progress on the Implementation Issues of ASEAN Harmonized Product

“Post Marketing Alert System-PMAS”

(1) Implementation of the PMAS

→ Area: - quality and safety
→ Member participation: - urge for an active participation of All
→ Progress rpt – on the past 2 years of the Alerts

(2) Sharing & Close cooperation

→ with other ASEAN-PWGs
→ request the ASEC to do the coordination activity
Outcome (5)

Other Progresses of the PPWG (1)

- ASEAN Regulatory Science Training
  ➔ a need of Members
    - on a Training for Capacity Building /Strengthening
    - on a Training Module, which could be used further for establishment of National Training Centre in the Member Countries
    - on a Training Support, for the Trainers from Member Countries
  ➔ Requested Philippines to take lead and work on Training Module
Outcome (6)

Other Progresses of the PPWG (2)

- ASEAN-US Cooperation on Pharmaceuticals
  → discussed and drafted the *Matrix of Training Needs* to propose for consideration
  → requested ASEC to explore further for technical assistant/capacity building programme for CLMV

- Cooperation with International Org. & Dialogue Partners
  → Vaccine Chapter
  → Combating the Counterfeit Drugs
Outcome (7)

Other Progresses of the PPWG (3)

- **Redefining the Structure**
  - structure and arrangement of the PPWG
  - composition of Participants in the Meetings
  - to facilitate Leader Mandate & Regional Economic Integration

- **Future Initiative for Integration of P’cal Sector in ASEAN**
  - initiative towards the ASEAN Economic Integration
  - request Members to provide Input on future Initiative & Strategies
  - will be discussed further in 15th PPWG meeting
Outcome (8)

Update Progresses of the ASEAN

- New Secretary-General of the ASEAN
  → H.E. Dr. Surin PITSUWAN (Th)
  → Term of 2008-2012

- Mandate / Facilitation towards AEC
  → AEC Blueprint
  → AEC Scorecard
  → ASEAN Charter
  → ASEAN Trade Facilitation Work Programme
  → ASEAN Trade in Goods Agreement (ATIGA)

- New Rep. of ASEC to the PPWG
  → Ms. Shirley Vincent RAMESH
ASEAN-PPWG and ICH-GCG (1)

- GCG Update to the 14th 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 → RHI’s Profile
    • Implementation of ICH gls. In non-ICH region
    • Update on future of GCG
    • Training / Capacity-building Implementation
Outcome (10)

ASEAN-PPWG and ICH-GCG (2)

ICH Update

- Group meeting & not-meeting in Yokohama (Oct.28-Nov.1, 2007)
- request for comment on Step 2-ICH Tech.gls (by Apr.08)
  - Q4B Annex 2
  - Q4B Annex 3
  - Annex to Q8
Outcome (11)

- recommendation to the 14th PPWG (1):
  → to note the GCG Update, presented by Co-Chair
  → to note the following matters, in particular:
    • RHI pre-meeting Report
    • RHIs’ update
    • Future of the GCG
    • ICH current Working topics

→ on RHI Profile
  • to view (the good, informative, right & direct messages from each RHI)
  • make use of RHIs’ Profile (will be posted on ICH webpage (www.ich.org))
  • to help finalize the ASEAN Profile before May 08

→ Lead Countries to fill in “ASEAN Harmonization Topics”
→ then, submit to the Co-Chair of PPWG by the end of Apr.08
**Outcome (12)**

**ASEAN-PPWG and ICH-GCG (4)**

- recommendation to the 14th PPWG (2):

  ➔ on Training & Capacity-building
    - to note 2 APEC’s Training projects
    - to note a request from PANDRH

    ➔ consider to Apply for participation in those Trainings
    ➔ consider to Requests the GCG for Speakers/Trainers

  ➔ on Step 2 of those 3 ICH Tech. gls.
    - to study
    - to comment directly to the ICH

    ➔ by Apr. 08, if any!
Outcome (13)

- PPWG:

  ➔ noted the progress of the GCG

  ➔ requested the Lead Countries:
    • to fill in the ASEAN Harmonisation Topics (ASEAN Profile)
    • send to Co-Chair of PPWG by 30 April 2008
Outcome (14)

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