

# Regional Update – **ASEAN PPWG**

by

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**The ICH-Global Cooperation Group Meeting  
Portland Marriott Downtown Waterfront Hotel, Oregon, USA  
03 June 2008**

# Outcome

**The 14<sup>th</sup> 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
  - 4<sup>th</sup> Meeting of ASEAN Taskforce on MRA-BA/BE Studies
  - Technical Discussion on :-
    - *Q&A on ACTD-Quality*
    - *Q&A on ASEAN Technical guidelines*
  - 5<sup>th</sup> Meeting of the ASEAN Taskforce MRA - GMP Inspection
  - Dialogue “IWG & P’cal Industry”
  - 9<sup>th</sup> IWG Meeting



## Outcome (2)

### 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 15<sup>th</sup> 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

## Outcome (9)

### ASEAN-PPWG and ICH-GCG (1)

- **GCG Update to the 14<sup>th</sup> 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)

### ASEAN-PPWG and ICH-GCG (3)

#### - recommendation to the 14<sup>th</sup> 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](http://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 14<sup>th</sup> 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)

### ASEAN-PPWG and ICH-GCG (5)

#### - 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 15<sup>th</sup> Meeting
  - Date → *Jul./Aug. 2008*
  - Venue → *Brunei Darussalam*

*Thank You*

