



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)



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

with the same Co-Chair
Yuppadee JAVROONGRIT
(Thailand)



Outcome (3)

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



Outcome (7)

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)

ASEAN-PPWG and ICH-GCG (4)

- 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

