



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



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



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



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**

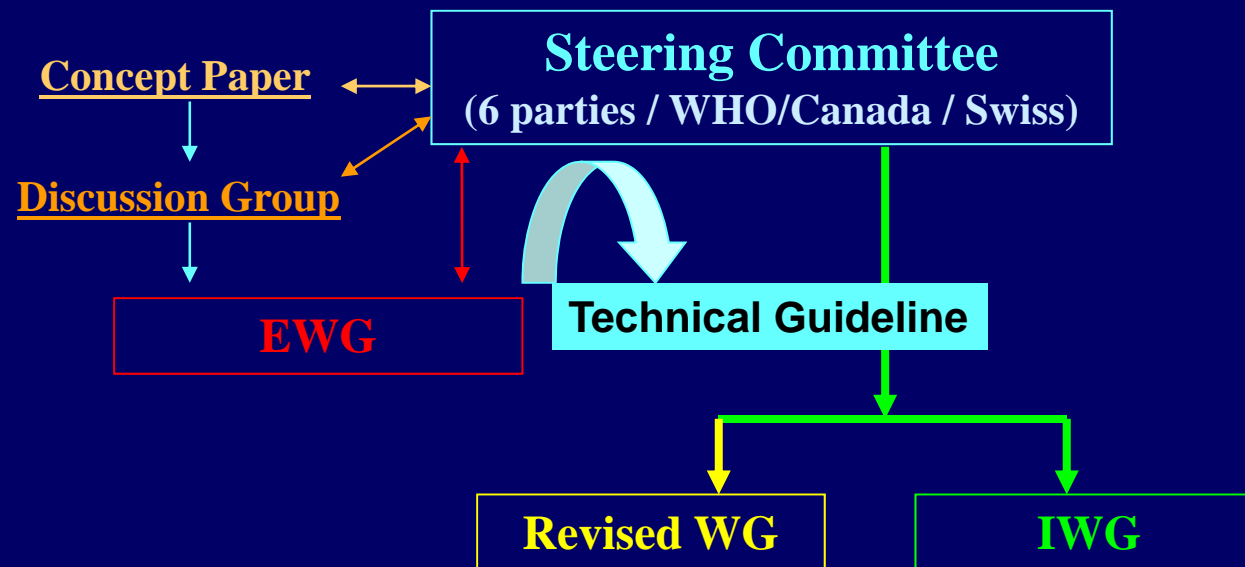
- RHI pre-meeting rpt
- Stability dev.
- RHIs' participating in EWGs
- Query from Indian Regulatory Authority
- **Training & Capacity-building** (+ *ICH-GCG Training Opportunities and Harmonisation Events*)
- **RHI Survey** (+ *RHI Global Questionnaire of ASEAN/PANDRH/GCC-DR/SADC-PHI, +Profile Table*)

→ **ICH Update**

- Current Working Topics
- Openness
- Working Structure



ICH Working Structure





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 12th 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 !)

Outcome (7)

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

Thank You

