Regional Update – ASEAN PPWG

by

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The ICH-Global Cooperation Group Meeting
Yokohama Royal Park Hotel, JAPAN
06 June 2006
Outcome from
The 11th PPWG Meeting
March 2006, Vietnam
Outcome (1)

• **participants** ~ 300 from 9 countries

• **back to back activities**
  - Focus Discussion Group:
  - Dialogue on Vaccine b/w ASEAN & WHO
  - Dialogue with Industry
  - 6th IWG Meeting
  - 2st ASEAN MRA Taskforce on GMP Inspection
Outcome (2)

Progress on the Implementation Issues of ASEAN Harmonized Product

**ASEAN BA/BE Studies**

- ASEAN MRA Taskforce on BA/BE Studies - *formed*

- **TOR – drafted and revising**
  - Definition of a comparator product/ ASEAN Comparator Product;
  - Decision Tree in Determining Comparator Products at ASEAN and National Level
  - List of ASEAN Comparator Products

- **Next Meeting** – consideration/adoption of TOR and Framework
Outcome (3)

**ASEAN Stability Guideline & ACTD Quality**

- **Climatic Zone**
  - known, from GCG-update, on Zone IVa & IVb
  - agreed to stay at 30c/75%RH

- **Q&A forum :-**
  - agreed for a formation
  - involving group of Experts, at National and/or Regional level
  - to resolve Implementation issues

- **Next Meeting**
  - consider/finalize the Q&A doc.
**Outcome (4)**

**Progress on the Implementation Issues of ASEAN Harmonized Product**

**“Dialogue with Industries” and “the 6th IWG Meeting”**

(1) **ACTD implementation**
- agreed to flexible over and above the ACTD
- ICH-CTD will be accept for specific categories of products
- need Common Understanding for def. of the specific categories

(2) **APAGEs Framework Formation**
- agreed on its importance
- aware of Resources constraints
- decided to defer to a later stage
Outcome (5)

Progress on the Implementation Issues of ASEAN Harmonized Product

“Dialogue with Industries” and “the 6th IWG Meeting” (con’t)

(3) IWG-Industry Dialogue

- an open forum to hear / discuss with Industries, regarding Implementation
- APC (ASEAN Pharmaceutical Club) & MNC (Multi National Grouping) - ASEAN Industries
- agreed in Dialogue/accepted by PPWG:-
  - the Dialogue will be continued
  - Tech. issues related to ACTD will be handled by Lead Countries
  - Non-tech. issues be discussed at National Level → NRA & Industry
  - For Non-tech. issues that need Common Recommendation/Decision → PPWG

(4) Next Meeting

- consider on “Flexibility”, “Definition of Specific Categories of Product”
Outcome (6)

Activities related to the ASEAN Healthcare Integration Roadmap

The 2nd Meeting of the ASEAN MRA Taskforce on GMP Inspection
- endorsed “TOR”, and “draft outline” of ASEAN Sectoral MRA on GMP Inspection
- expected finalization of the Sectoral MRA, agree, and sign by End of 2007

Post Marketing Alert (PMA) System
- adopted the Format
- agreed to implement, as a Voluntary sharing of information, for trial period of 1 yr
- agreed that System could be considered as Formal system in the future
- agreed to have separate Glossaries for P’cals, Cosmetic, TM&HS
Outcome (7)

Cooperation with International Org./Dialogue Partners

**WHO-ASEAN Harmonization Project**

- informed a reassignment of work at WHO HQ
- accepted the defer of *ASEAN Guidance on Reference Drug Info. project* (by WHO)
- requested and waiting WHO’s nomination on New Officer

**Vaccine Chapter**

- expressed appreciation to WHO’s willingness to assist ASEAN
- focus on capacity building in the area of vaccine evaluation
- agreed to include Vaccine Chapter in PPWG’s activities
- appointed **Regional Focal Point** for coordination with WHO
Outcome (8)

Cooperation with International Org./Dialogue Partners

ASEAN-PPWG and ICH-GCG

- noted the update & recommendation on GCG (by Co-Chair of PPWG)
- considered and then:-
  - decided to remain at 30c/75% RH (on update info. of WHO/ICH on Climatic Zone IVa and IVb)
  - decided not to sent Rep. to Q10EWG, reasons:-
    - PPWG \( \rightarrow \) observer in the GCG
    - financial constraints
    - PIC/S \( \rightarrow \) might already involve with the ICH, in this regards
  - agreed to let Member to directly submit own comments to ICH (on Step 2 of ICH stepwise activities on ICH Draft Guideline)

- request :- (on draft GCG Strategy on Training and Capacity Building related to the Use of ICH Guideline Document)
  - Members to submit comments/inputs to the Co-Chair (PPWG)
  - Co-Chair, after compilation of inputs, to seek guidance/endorsement from the Chair (PPWG)
    before submitting to GCG
Outcome (9)

**Major Observation and Recommendation**

**Acknowledgment**

- Valuable contribution in PPWG’s activities
  - Dr. Valerio REGGI - WHO
  - Ms. Fudziah ARIFFIN - My
  - Ms. Josephine K. SARAU - Ph

- agreed on Date & Venue (Indonesia) of the next Meeting
Latest Info.

• The Next Meeting
  - New Date → Nov. 06
Thank You