



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)

Progress on the Implementation Issues of ASEAN Harmonized Product

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
- awared 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 2st 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 → observer in the GCG**
 - **financial constraints**
 - **PIC/S → 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

