Regional Update – ASEAN PPWG

by
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The ICH-Global Cooperation Group Meeting
Westin Hotel Michigan Avenue, Chicago, USA
8 November 2005
Outcome from
The 10th PPWG Meeting
Aug. 2005, Singapore
Outcome (1)

- **participants** ~ 300 from 10 countries

- **back to back activities**
  - Technical Discussion Meeting: *Session on Stability Q&A*
  - 5th IWG Meeting
  - 1st ASEAN MRA Taskforce on GMP Inspection
  - 4th ASEAN Regulatory Seminar:
    - "Assuring the Quality of Medicines and Vaccines"
      - PIC/S - International Inspection Issues and Expectations by *Mr. Robert TRIBE*
      - Developing Countries Vaccine Regulators (DCVR) Network and the Regulatory Requirements for Vaccines by *Dr. Liliana CHOCARRO*
      - Article 58 of the new EU Legislation by *Dr Valerio REGGI*
      - Regulatory Perspectives on Chemical versus Biologic Products by *Philip K. NGAI, PhD*
Outcome (2)

• **noted and agreed** *Highlights of*
  - ASEAN Economic Minister (AEM) Meeting
  - ASEAN Senior Economic Official (SEOM) Meeting

• **noted** *progress and recommendation of*
  - 25th and 26th ACCSQ meeting

• **agreed to discuss, after endorsed,** *ACCSQ recommendation*
  - ASEAN Policy on Standards and Conformance
Outcome (3)

Progress on the Implementation Issues of ASEAN Harmonized Product

ASEAN BA/BE Studies

- noted following Recommendation:-
  (i) to harmonize …
  - Definition of a comparator product/ASEAN Comparator Product;
  - Decision Tree in Determining Comparator Products at ASEAN and National Level
  - List of ASEAN Comparator Products

(ii) not to have an ASEAN priority list

- agreed to set a Task Force to follow-up on
  - all Recommendations
  - mutual acceptance of BE Study Data Evaluation Report in ASEAN
Outcome (4)

Progress on the Implementation Issues of ASEAN Harmonized Product

ASEAN Stability Guidelines & ACTD Quality

- **noted and requested that** :-
  - Id to revise the existing Q&A and circulate to Members for comments
  - Members to feed-back by Dec.05
  - Finalized Q&A to submit for further discussion

- **endorsed** :-
  - establishment of “Advisory Group of Expert Committee”
Outcome (5)

Progress on the Implementation Issues of ASEAN Harmonized Product

The 5th IWG Meeting

- **noted & agreed on** ACTD Implementation :-
  - ACTD implementation → full acceptance of its Format/ACTR/guidelines, but not an evaluation for MA
  - ACTD is the standard format for acceptance in the region
  - IWG to hold back-to-back dialogues with industry, at its future Meeting

- **noted, welcomed, & requested** the Training needs /syllabus
  - establishment of “ASEAN Regulatory Sciences Training Scheme”
  - exploring a mechanisms to ensure the sustainability of the Scheme
Progress on the Implementation Issues of ASEAN Harmonized Product

The 5th IWG Meeting (con’t)

- noted & requested on APAGE Framework “ASEAN Pharmaceuticals Advisory Group of Experts”
  - proposed framework for the formation of APAGEs
  - Members to feed-back by Dec.05
  - discuss further
Outcome (7)

Activities related to the ASEAN Healthcare Integration Roadmap

The 1st Meeting of the ASEAN MRA Taskforce on GMP Inspection

- noted the report of the Taskforce
- requested Members to feed-back on proposed “Terms of Reference and Framework” by Dec.05
- agreed for conducting the GMP implementation survey :-
  - to identify Situation, and
  - to work out the roadmap for improvement of GMP infrastructure
Outcome (8)

ASEAN-PPWG and ICH-GCG

- noted the update & recommendation on GCG (by Co-Chair of PPWG)

- considered and then suggested :-
  - the request for input from ICH should be sent to each individual countries as soon as possible for ample time for consideration
  - and any comments that represents ASEAN at the GCG should be sent to Co-Chair for compilation and circulation to all Member Countries for agreement by consensus before presenting to GCG

- recommended
  - Member Countries to submit any proposals on training and capacity building to GCG as individual country request
Outcome (9)

**Vaccine Chapter**

- **noted** WHO’s Presentation on Developing Countries’ Vaccine Regulators (DCVR) Network and Regional Initiatives and Vaccine Regulation
- **agreed**
  - a need to establish a strong cooperation amongst NRAs in ASEAN Member Countries on Regulation of Vaccines
  - a need to look into more details on “Vaccine Chapter” & “Direction” for cooperation b/w ASEAN and WHO
  - to hold a dialogue on Vaccines back-to-back with the 11th PPWG Meeting
- **assigned** Id & Th
  - to assist in following-up the matter with the WHO
Outcome (10)

• **Major Observation and Recommendation by the PPWG**
  
  - **noted / encouraged** input & further action on *ASEAN Guidance on Reference Drug Information project* of WHO-ASEAN Harmonization project
  
  - **noted**
    
    - with appreciation the implementation of sub-programme on pharmaceuticals under **EC-ASEAN Regional Cooperation Programme on Std., Quality, and Conformity Assessment**
    
    - a conduct of Workshop on GRP for Pharmaceuticals under *ASEAN-Australia Development Cooperation Programme (AADCP)*
    
    - a concerns over the delay in implementing *ACCSQ-US Action Plan* and noted that ACCSQ would take further action with US representative on this regard
  
  - **recommended** ACCSQ to explore cooperation in the Pharmaceuticals with other Dialogues Partners
  
  - **encouraged** Members to propose Activities for ACCSQ’s consideration.
Outcome (11)

- **Major Observation and Recommendation by the PPWG (Con’t)**

  - **expressed** appreciation to Id, My, & Th for Supports / Assistance on Training to new Members

  - **agreed** to recommend to the ACCSQ to extend the Terms of Reference of the PPWG with the
    chairmanship by Malaysia and co-chairmanship by Thailand for another 3 years

  - **adopted** the Revised Work Programme

  - **agreed** on the next Meeting

    - Date → Feb. 06
    - Venue → Vietnam

YJ – 8 Nov. 05/Chicago
Thank You