Regional Update - ASEAN

by

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The ICH-Global Cooperation Group Meeting
Radisson SAS Hotel, Brussels, Belgium
10 May 2004
Outcome From The 9th PPWG Meeting Feb.05, Makati city, The Philippines
Outcome (1)

• **participants** ~ 300 from 9 countries

• **back to back activities**
  - 3 Focus Discussion Groups-FDG (Efficacy, ASEAN BA/BE, and Stability)
  - Implementation Working gr. Meeting
  - Technical seminar
    - Bioavailability / Bioequivalence by Nobuo Aoyagi, PhD
    - Pharmacovigilance by Kenneth Hartigan-Go, MD, MSc
    - Impact of Harmonization on Trade in the ASEAN Region by Ramon Vicente T. Kabigting
    - Global Design of Stability Testing & Risk-based Approach to Stability Evaluation by Manuel Zahn, PhD
Outcome (2)

- **noted and agreed** Highlights of
  - ASEAN Summit
  - ASEAN Economic Minister meeting
  - High Level Task Force (HLTF) → Healthcare Integration
  - Roadmap for the Healthcare Integration
  - ASEAN Framework Agreement for Priority Sector Integration

- **noted** progress and recommendation of
  - 24th ACCSQ meeting
  - 21st AWGTCP meeting
Outcome (3)

- **agreed** Recommendation of
  - FDG-Efficacy guidelines
  - FDG-BA/BE issues
  - FDG-Stability issues

- **agreed** Common & Specific Labeling Requirement
  and the needs for further discussion
Outcome (4)

Status of Implementation of the ACTD

- noted Fully Implementation Intention
  → MY & SG by 31 Dec. 2005
  → TH by 31 Dec. 2006
  → ID & VN by 31 Dec. 2007
  → remaining countries by 31 Dec. 2008

- noted the Training needs
  - Survey
  - Draft Syllabus/Strategic recommendation/Implementation’s Option

- agreed and requested the further follow-up actions

YJ
Outcome (5)

- **noted and agreed** MRA for P’cal Sector in ASEAN
  - the decision made at Head Delegation meeting
  - MRA for GMP Inspection (*Chairmanship- MY & SG*)
  - aim for signing by Ministers by end of 2007

- **agreed and endorsed** IWG’s proposals/requests
  - forming *ASEAN Pharmaceutical Advisory Gr. of Experts*(APAGEs)
  - revising *TOR*
  - extending for a new term(2 yrs.) with same Chairmanship(SG & ID)

YJ
Outcome (6)

**ASEAN-PPWG and ICH-GCG**

- noted the update of GCG activities (by Co-Chair of PPWG)

- considered and then agreed :-
  - to nominate the Co-Chair of PPWG to be the Permanent Representative to all GCG Meeting
  - in the event that the Co-Chair of PPWG could not attend the GCG, the Chair and Co-Chair of IWG will attend
Outcome (7)

**Vaccine Chapter**

- **noted** *WHO’s Intention* to share with PPWG on Progress of Developing Countries’ Vaccine Regulators (DCVR) Network (formalized in Sep.04, BKK, Thailand)

- **agreed** *Proactive role*
  - establishing and strengthening *Regulatory system for Vaccines*
  - invite the WHO Expert to attend & present in 10th PPWG

- **considered** *the Seminar on Vaccine*, back to back with the 10th PPWG
Outcome (7)

- **Major Observation and Recommendation by the PPWG**
  - noted / requested further action of WHO-ASEAN Harmonization project
  - noted the pertaining Meeting on EC-ASEAN Regional Cooperation Programme on Std., Quality, and Conformity Assessment on Pharmaceutical Sector
  - agreed to recommend the ACCSQ to seek for more Funding from its Dialogue Partner to support the works of PPWG
  - noted/expressed appreciation to APC(ASEAN Pharmaceutical Industry Club) for willing to support PPWG
  - adopted the Revised Work Programme
Outcome (8)

- agreed on the next Meeting
  - Date → Aug.05
  - Venue → Singapore
Thank You