

Regional Update - **ASEAN**

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

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*

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 Ministeres 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)*

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

