



Regional Update – **ASEAN PPWG**

by

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The ICH-Global Cooperation Group Meeting
Westin Hotel Michigan Avenue, Chicago, USA
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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



Outcome (6)

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*



Thank You

