

# **ASEAN Harmonization *Update***

by

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**The ICH-Global Cooperation Group Meeting  
Yokohama Royal Park Hotel, JAPAN  
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# Outcome From The 8<sup>th</sup> PPWG Meeting *July 2004, BKK, THAILAND*

# Outcome (1)

- ~ 300 participants from 9 countries
- informed *Highlights of the ASEAN Economic Cooperation*
  - ASEAN Economic Community
  - High Level Task Force (HLTF) → *Healthcare Integration*
- noted *endorsement of ACCSQ*
  - ACTD's Organization
  - Guideline on Analytical Validation
  - Guideline on Process Validation

# Outcome (2)

- **noted *info. & exp.*** “*Implementation of the TRIPs Agreement, Article 39.3*”
- **agreed *matters arising from the 7<sup>th</sup> PPWG Meeting***
  - **ACTD on Quality-criteria for critical excipients**
- **confirmed/adopted *final draft***
  - **ASEAN Guideline on Stability Studies**
  - **ASEAN Guideline on BA/BE Study**

# Outcome (3)

- **noted on *Pending & New Efficacy Guidelines***
  - agreed “members to review *Pending GLs* and feedback”
  - agreed “to form WG to work→report to next PPWG Meeting”
- **agreed on *ACTD Implementation***
  - Fully → by 31 December 2008
  - Numbering for ACTD → no changes/amendments
  - Encouraged → use *ASEAN- X formula*

# Outcome (4)

- **asked *IWG* to work further on**
  - Labelling requirement
  - Training needs analysis → support Members in implementing the ACTD
- **noted on *MRA* for *P'cal Sector in ASEAN***
  - potential areas of MRA for possible dev.
  - assigned focal point and discuss in the next meeting
- ***cooperation with relevant International Org./Dialogue Partners***
  - WHO
  - GCG
  - EC

# Outcome (5)

- *ASEAN-PPWG and ICH-GCG :-*
  - *noted the activities and TOR of the GCG*
  - *considered GCG's invitation for sending Permanent Rep. to participate in GCG activities*
  - *then agreed :-*
    - *participation of the PPWG rep. in GCG activities should be as an Observer*
    - *PPWG's Chair will inform the GCG*

# Outcome (6)

- *agreed on the next Meeting*
  - *Date → Feb.05*
  - *Venue → the Phillipines*

# The next Meeting

## The 9<sup>th</sup> ACCSQ/PPWG Meeting (1)

- **Date / Venue** → *Feb. 05 / Manila, the Philippines*
- **Major Topics :-**
  - **Mandate from ASEAN leader/AEM/SEOM/HLTF/ACCSQ**
  - **BA/BE study:- selection of Comparator prod.Active subs.**
  - **Efficacy Guidelines**
  - **Implementation status / Training needs**

## The 9<sup>th</sup> ACCSQ/PPWG Meeting (2)

- **Major Topics :- cont....**
  - **Possible MRA for P'cal in ASEAN**
  - **WHO-ASEAN SmPC project update**
  - **EC-ASEAN Cooperation Programme update**
  - **Assignment *Permanent Rep. of PPWG* (*as an Observer*) to the GCG**
  - **Extension of PPWG Term**
  - **Date / Venue of the next Meeting**

## The 9<sup>th</sup> ACCSQ/PPWG Meeting (3)

- **Back to Back/Parallel Activities:-**
  - IWG meeting
  - Stability GL meeting(?)
  - BA/BE workshop
  - Efficacy GLs workshop
  - Seminar

# Special Remark

# Participation of PPWG's Rep. to the GCG

- as an Observer
- Comment of PPWG's Rep. in the GCG meeting  
→ *being an individual opinion*
- The PPWG's Chair → nominated Co-Chair as the PPWG observer  
to all GCG meetings *until informed otherwise*

