ASEAN Harmonization Update

by
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The ICH-Global Cooperation Group Meeting
Yokohama Royal Park Hotel, JAPAN
16 November 2004
Outcome
From
The 8th 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 7th 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

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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 Philippines
The next Meeting
The 9th ACCSQ/PPWG Meeting (1)

- **Date / Venue**: Feb. 05 / Minila, 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 9th 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 9th 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
Thank You
Thank You
Thank You
Thank You