

Regional Update – *ASEAN PPWG*

by

Yuppadee JAVROONGRIT, Ph.D.

Co-Chair of ACCSQ/PPWG, ASEAN

Drug Control Division, ThaiFDA, Thailand

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Background

ASEAN

= Association of Southeast Asian Nations

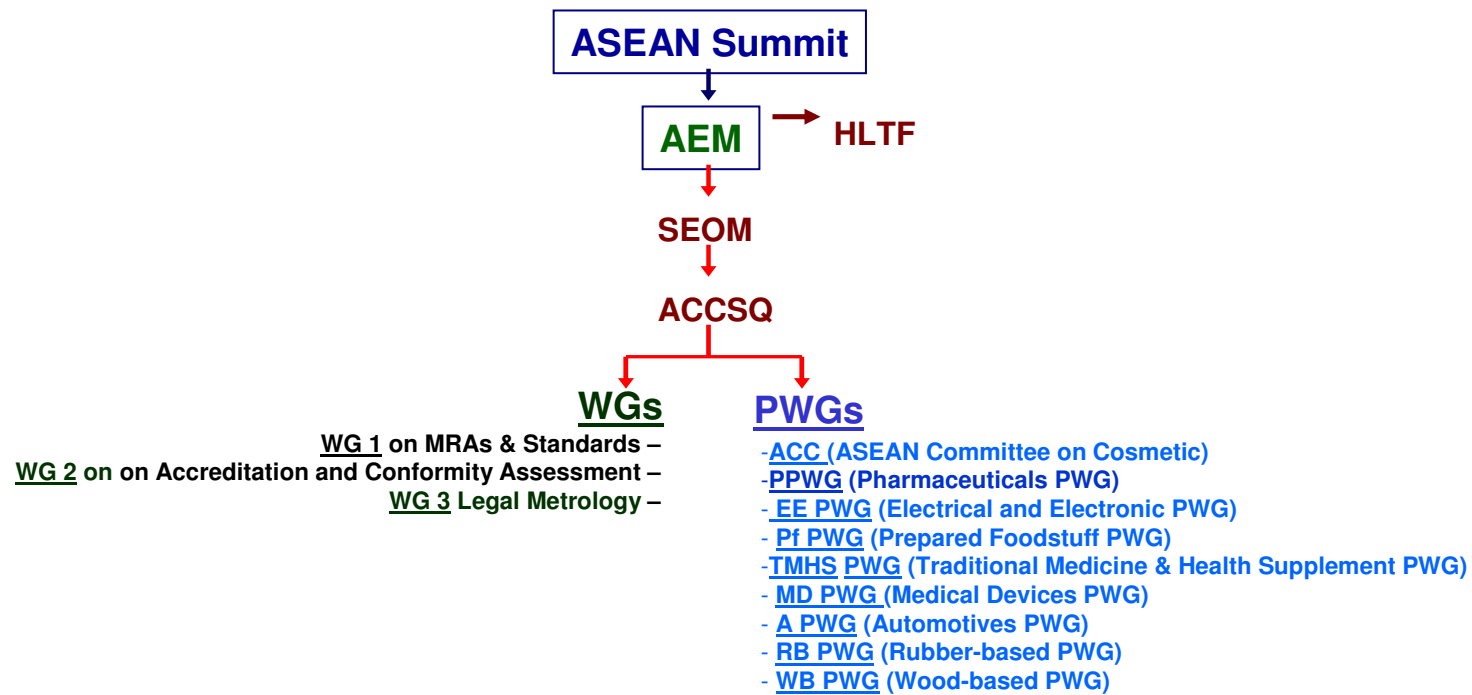
Member



- Brunei Darussalam
- Cambodia
- Indonesia
- Lao PDR
- Malaysia
- Myanmar
- Philippines
- Singapore
- Thailand
- Vietnam

Total population ~ 550 million

Economic Cooperation in ASEAN





Ultimate Goal of the ASEAN

ASEAN Summit

ASEAN Leader



ASEAN Economic Community (AEC)

“by the year 2015..... ASEAN will be

Single Market and Single Production Base

(Free flow of Goods, of Services, of Investment, of Capitals, of Skilled Labour)

Mandate / Facilitation towards AEC

- AEC Blueprint
- AEC Scorecard
- ASEAN Charter
- ASEAN Trade Facilitation Work Programme
- ASEAN Trade in Goods Agreement (ATIGA)

The ASEAN – PPWG (1)

ACCSQ/PPWG

**ASEAN Consultative Committee
for Standards and Quality /
Pharmaceutical Product Working Group**

The ASEAN – PPWG (2)

- Establishment → 1999
- Aim & Target :
 - for **Generic, Modified, and NCEs & Bio. products**
 - after achieved ‘**ASEAN Harmonized Product**’



‘**Trial Implementation**’



Full Implementation *by 31 Dec. 2008 !*

The PPWG – *Lead country & Assignment (1)*

Chair country : Malaysia

Co-Chair country : Thailand

- **ACTR** : *Quality* → Indonesia
Safety → Philippines
Efficacy → Thailand
- **ACTR-Guidelines** : *Analytical Validation* → Thailand
BA/BE Studies → Malaysia
Process Validation → Singapore
Stability Study → Indonesia



The PPWG – *Lead country & Assignment (2)*

- **ACTD** : *Overall ACTD & ACTD Organization* → Thailand
Administrative & Glossary → Malaysia
Quality → Indonesia
Non-Clinical → Philippines
Clinical → Thailand
- **IWG** : Singapore (*Chair*)
Indonesia (*Co-Chair*)
- **MRA-GMP** : Singapore / Malaysia (*Co-Chairs*)
- **MRA-BA/BE**: Malaysia/Indonesia (*Co-Chairs*)
- **Training** : Philippines
- **Variation Guideline** : Malaysia

The PPWG– Agreement

- Harmonized Key Areas
- Format for ACTR & ACTD
- Content of ACTR/ACTD/Glossary of Term
- ASEAN Harmonized Products
(ACTR + ACTD + Glossary of Term + Technical Guidelines)
- Implementation – Trial period (July 04 onwards)
- Full Implementation **by 31 Dec. 08**



PPWG – Agreement on Technical Guidelines

“Guideline – Quality”

→ based on *International Tech.gls.*

→ drafted 4 *ASEAN Quality gls.*

(1) Analytical Validation guideline

(2) BA/BE Studies guideline

(3) Process Validation guideline

(4) Stability Study guideline



PPWG – Agreement on Technical Guidelines

“Guideline – Safety”

→ adopted ICH-Safety guideline (15 GLs)

“Guideline – Efficacy”

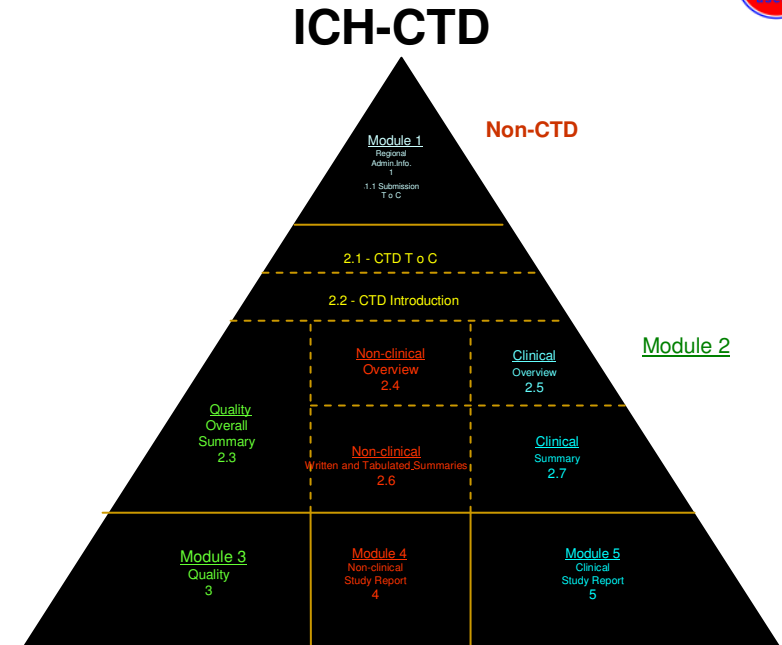
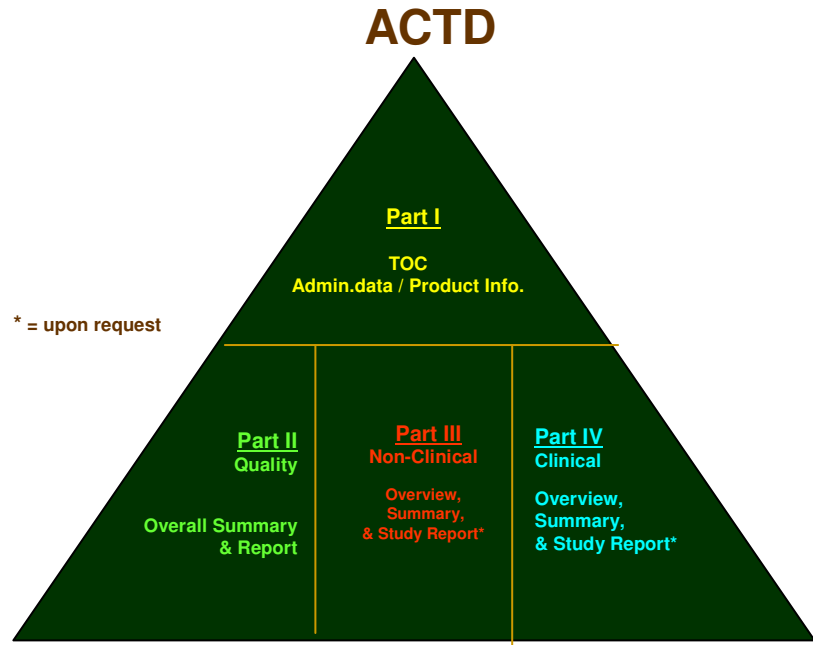
→ adopted 11 ICH-E guideline (E1, E2A, E2C, E3, E4, E6-E11)

→ accepted as Ref.gl. 4 ICH-E guideline (E2C(A), E2D, E2E, E12A)

→ not adopted 2 ICH-E guideline (E2B(M), E5)

ACTD

**The part of
marketing authorization application dossier
that is common to
all ASEAN member countries**



ICH-CTD is accepted for NCE & Biotech. Product

- with ACTD-part I
- compliance to ASEAN – Quality guidelines



Update / Progress



Outcome

The 15th PPWG Meeting (*Jul.08, Brunei Darussalam*)
“related to the ICH”



Outcome (1)

- **participants** from 9 countries (*Regulators + Industries*)
- **official opening** by **Dato Seri Setia Haji Suyoi bin Haji Osman**,
(Minister of Health, Brunei Darussalam)
- **back to back activities :**
 - **Head of Delegations (HOD) Meeting**
 - **the 5th Meeting of ASEAN Taskforce on MRA-BA/BE Studies**
 - **Technical Discussion on :-**
 - *Q&A on ACTD-Quality*
 - *Q&A on BA/BE Technical Guideline*
 - **the 6th Meeting of the ASEAN Taskforce MRA - GMP Inspection**
 - **Dialogue “IWG & P’cal Industry”**
 - **the 10th IWG Meeting**



Outcome (2)

Progress on the Implementation Issues of ASEAN Harmonized Product

“ASEAN MRA for Pharmaceuticals”

(1) ASEAN MRA-BA/BE Studies

- Framework for Mutual Acceptance of the *BA/BE Study Report*
- Agreement on *Reporting Format, Criteria for Inspection*

(2) ASEAN MRA-GMP Inspection

- Agreement on Final Draft “Sectoral MRA-GMP Inspection”
- *2 yrs. deferral of implementation*
- Requested the completion of the *National Consultation of Members*
- proposing for the Signing in the coming ASEAN Submit



Outcome (3)

Progress on the Implementation Issues of ASEAN Harmonized Product

“The Implementation Working Group-IWG”

(1) Mechanism for the revision of ASEAN Tech. gls.

- discussed and agreed to amendment further
- planned for adoption – *at the 16th PPWG Meeting*

(2) ASEAN Guideline on Variation

- Agreed to develop
- Malaysia will lead the Task

Outcome (4)

Other Progresses of the PPWG

- **Redefining the Structure & new TOR**
 - new Role “Joint Sectoral Committee”
 - future Initiative for Pharmaceutical Sectors in AEC

- **Cooperation with International Org. & Dialogue Partners**
 - WHO-Vaccine Chapter
 - WHO-Combating Counterfeit Drugs
 - ASEAN-US Cooperation on Pharmaceuticals

Outcome (5)

ASEAN-PPWG and ICH-GCG (1)

- GCG Update to the 15th PPWG → by PPWG's Co-Chair
- presented Topics :

→ GCG Meetings (Agenda/Venue/RHIs participation)

→ GCG Update

- Regulator Forum report
- RHI pre-meeting report
- RHI update
- Comment on Step 2-ICH Tech. gl.
- Stability gl. development
- RHI Survey update → Review of RHI's Profile
- GCG procedural matters
- Training / Capacity-building Implementation
- ICH update report



Presentation to PPWG

Regulator Forum Report

- 1) **invited both RHIs and DRAs** (willing & implementing ICH GLs)
- 2) **friendly and openness** → *build Trust & Confidence !*
- 3) **discussion on Challenge in Implementing ICH GLs**
 - translation into Local Language (language, and Tech. aspect)
 - accurate interpretation of Principles
 - how to keep update with ICH GLs
 - need various Kind & particular Level of Training
- 4) **conclusion :**
 - good
 - need participation & contribution
 - be requested for continuation

Presentation to PPWG

PPWG



The ICH Update

- 1) the EWGs that met in Portland
- 2) MedDRA (current status, free for DRAs, MSSO-Training)
- 3) Step 2-ICH Tech.gls.
 - deadline “end of Sep.08” (Q4B Annex 4A, 4B, 4C, 5)
 - deadline “end of Dec.08” (E2F)
 - participation in Webinar [on E2F & M3(R2)]
 - request to send Comment to ICH Secretariat (Dr.Ronan)
- 4) Step 4-ICH Tech.gls. (Q4B Annex 2&Annex 3, Q10, Q14 Q&As)
- 5) Source of ICH Tech.gls. (→ www.ich.org)

Presentation to PPWG

Recommendation to the 15th PPWG (1)

- to note the GCG Update, presented by PPWG Co-Chair
- to note, in particular ;
 - RHI pre-meeting report
 - RHIs' update (activities and progress in other RHIs)
 - Future of GCG
 - ICH Current Working topics
- Rep. to prepare for “WHO-Consultative Meeting on Stability gl.
- to consider Requesting GCG “Training & Capacity-building”



Presentation to PPWG

Recommendation to the 15th PPWG (2)

- to note “Step 2 & 4 –ICH Tech.gls.” and take relevant actions
- to consider and approve “ASEAN Profile”
(for submission to be placed in ICH-Website)
- to note the Regulator Forum ;
 - existing
 - seeking “Clarification & Answer/Advise & Guidance for Implementation” the ICH-Tech.gls.

Outcome (6)

ASEAN-PPWG and ICH-GCG (2)

PPWG :

→ noted :

- the progress of the GCG
- development of “ASEAN Profile” and its aim in posting on ICH Website
- recommendations by the PPWG Co-chair

→ requested the Members and Lead Countries:

- to review the Draft Profile
- submit comment and input to Co-Chair of PPWG by 30 Sep.08

Outcome (7)

- **PPWG agreed** on the next Meetings
 - the 16th PPWG
 - around *May 2009*
 - *in the Philippines*

 - the 17th PPWG
 - around *Nov.2009*
 - *in Thailand*

Recommendation to the GCG

- noted the progress of the ASEAN-PPWG
- noted the final ASEAN-PPWG Profile
- consider to support the Training Needs of ASEAN-PPWG
 - (1) Q5 C (Stability Test of Biotech. products)
 - (2) Q9 (Quality Risk Management)
 - (3) MedDRA (for Clinical Trial)

Thank You

