ASEAN PPWG
Regional Update on ICH-related Matters

by
Yuppadee JAVROONGRIT, Ph.D.
Co-Chair of ACCSQ/PPWG, ASEAN
Drug Control Division, ThaiFDA, Thailand

The ICH-Global Cooperation Group Meeting
Sokos Viru Hotel, Tallinn, Estonia
8 June 2010
Topics

- the ASEAN & PPWG
- progress “ICH-Training in ASEAN”
- upcoming PPWG meeting
- Seminar b/b with PPWG
The ASEAN
ASEAN

= Association of Southeast Asian Nations

Member

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

total population ~ 580 million
The ASEAN

- establishment → 8 August 1967
- population → ~580 mil. (8.7% of world pop.)
- area → 4.5 mil.Km²
- combined nominal GDP → >1.5 trillion USD
The ASEAN (1)

- **Objective:**
  1. accelerate the economic growth, social progress, and cultural development
  2. promote regional peace and stability

- **1995 – ASEAN Leaders reaffirmed that:**
  “Cooperative peace and shared prosperity shall be the Fundamental goals of ASEAN”
The ASEAN (2)

- **Fundamental principle:**
  1. Mutual respect for the independence, sovereignty, equality, territorial integrity, and national identity of all nations
  2. The right to lead its national existence free from external interference, subversion, or coercion
  3. Non-interference in the internal affairs of one another
  4. Settlement of differences or disputes by peaceful manner
  5. Renunciation of the treat or use of force,
  6. Effective cooperation among themselves
The ASEAN (3)

- Structure and Mechanisms

  - ASEAN Summit
  - ASEAN Ministerial Meeting
  - Senior Officials Committees
  - Technical Working Groups
The ASEAN (4) - Major Cooperation

ASEAN Summit
The Leader (Presidents, Prime Minister)

- Economic Cooperation-AEM
  Minister of Economic/Trade Ministry

- Political & Security Cooperation
  - Socio-cultural Cooperation
  Minister of Foreign Affairs Ministry
The ASEAN (5) – Economic Cooperation

WG1 on Mutual Recognition Arrangements (MRAs) & Standards –
WG2 on Accreditation and Conformity Assessment –
Scientific/Industrial Metrology Sub-WG –

WG1 on Mutual Recognition Arrangements (MRAs) & Standards –
WG2 on Accreditation and Conformity Assessment –
Scientific/Industrial Metrology Sub-WG –

- ACC (ASEAN Committee on Cosmetic)
- PPWG (Pharmaceutical PWG)
- EE PWG (Electrical and Electronic PWG)
- PI PWG (Prepared Foodstuff PWG)
- TMHS PWG (Traditional Medicine & Health Supplement PWG)
- Medical Devices & Equipment PWG
- A PWG (Automotives PWG)
- RB PWG (Rubber-based PWG)
- WB PWG (Wood-based PWG)
The ASEAN (6) – The AFTA

• endorsed → 1992
• purposed → to enhance Economic Cooperation
• strategic objective →
  “To increase the ASEAN region’s competitive advantage as a single production unit”
• target function → tariff, TBT, and NTB
The ASEAN (7) – the AEC (ASEAN Economic Community) (i)

- the 9th ASEAN Summit:
  - on 7 Oct. 03
  - signed the *Bali Concord II*
  - mandated timeline for AEC to be by the year 2020
    (timeframe is re-set to “2015”)
  - endorsed HLTF/ AEM’s recommendation: -
    - improving of the *Dispute Settlement Mechanism*
    - establishing 3 new units: *Legal unit, ACT, and ACMB*(or ACB now)
The ASEAN (8) – the AEC (ii)

- the Bali Concord II:
  - declared the establishment of ASEAN Community
  - ASEAN Community shall be comprised of 3 pillars:
    - political & security cooperation
    - economic cooperation
    - socio-cultural cooperation
  - declared the AEC is the realization of the end-goal of economic integration
The ASEAN (9) – the AEC (iii)

• the AEC:
  → aimed to: create stable, prosperous, and highly competitive ASEAN Economic region
  → shall:
    - establish ASEAN as Single Market and Production base
    - institute new mechanisms and measures to strengthen the implementation of its existing economic initiatives – AFTA, AFAS, and AIA
    - accelerate regional integration in the Priority sector
    - improve the Dispute Settlement Mechanism
    - implement HLTF’s recommendation
The Ultimate Goal of ASEAN

ASEAN Economic Community (AEC)
“by the year 2015….. ASEAN will be
Single Market and Single Production Base

- Free flow of Goods
- Free flow of Services
- Free flow of Investment
- Free flow of Capitals
- Free flow of Skilled Labour

Yupadee – 8Jun2010, Tallinn, Estonia
The PPWG
ASEAN Harmonization
The PPWG (1) – Full name

PPWG ➔ ACCSQ/PPWG

ASEAN Consultative Committee for Standards and Quality / Pharmaceutical Product Working Group
The PPWG (2) – Establishment

- **1992** AEM → ACCSQ
  - Working Groups (WGs)
  - Product Working Groups (PWGs)

- **1998** ACCSQ → initiated the PPWG

- **1999** ACCSQ → endorsed the PPWG
  - PPWG → started to function

- **2003, 2005 & 2009** ACCSQ → endorsed “2nd, 3rd, & 4th Term of the PPWG”
  - (same Chair & Co-Chair countries)
The PPWG (3) – Objective

“To develop harmonization scheme of Pharmaceuticals regulations of the ASEAN member countries to complement and facilitate the objective of AFTA, particularly, the elimination of Technical Barriers to Trade posed by the regulations, without compromising on drug quality, efficacy, and safety”

& facilitate the AEC !!!!
The PPWG (4) – *Principle, Scope, Output*

**Principle**  ➔ to promote “Registration”, “Trade”, & “Co-operation”  
                 ➔ to eliminate “TBT”

**Scope**  ➔ to harmonize “ASEAN Pharmaceutical Registration”

**Output**  ➔ ASEAN Harmonized Product

* (ACTR, ACTD, Glossary of Terms, GLs)
The PPWG (5) – Aim & Target

→ for Generic, Modified, and NCEs & Bio. products

→ after achieved ‘ASEAN Harmonized Product’

‘Trial Implementation’

Full Implementation by 31 Dec. 2008!

→ implementation supportive activities
→ capacity building
→ updating the Technical Guidelines
→ developing the MRA (Mutual Recognition Arrangement)
The PPWG (6) – Lead country & Assignment (i)

**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 (7) – Lead country & Assignment (ii)

- **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**: Indonesia / Malaysia *(Co-Chairs)*

- **Post-marketing Alert System (PMAS)**: Singapore / Malaysia
The PPWG (8) – Agreement

1. Harmonized Key Areas
2. ACTR & ACTD & Technical guidelines
3. Full implementation timeline
4. MRA-GMP Inspection
5. Vaccine chapter
6. on going tasks ;
   - MRA – BA/BE Testing
   - Variation guideline
   - updating the Technical guidelines
   - training activities
   - new area of harmonization i.e. biosimilar(?).....
The PPWG (9) – Working Scheme

Comparative study
on Registration Requirement & Regulation

Identification the “Key Area on Requirements”
for Harmonization

Assignment “Lead Countries”

“Lead Countries” Working

Member countries

The Meeting

Agreement
“ASEAN Harmonized Product”

Endorsement
(ACCSQ / SEOM / AEM /…)

Implementation
by Members

Yuppadee – 8 Jun 2010, Tallinn, Estonia
A set of Written Materials intended to guide applicants to prepare application dossiers in a way that is consistent with the expectations of all ASEAN Drug Regulatory Authorities
ACTD

The part of marketing authorization application dossier that is common to all ASEAN member countries
S&E Technical guideline to ACTR

Guideline - **Safety**

→ adopted 15 *ICH-Safety GLs*

Guideline - **Efficacy**

→ adopted 11 *ICH-Efficacy GLs* (E1, E2A, E2C, E3, E4, E6-11)
→ accepted as Ref.gls. 4 *ICH-Efficacy GLs* (E2C(A), E2D, E2E, E12A)
→ not adopted 2 *ICH-Efficacy GLs* (E2B(M), E5)
progress
“ICH-Training in ASEAN”
**ASEAN Activities :- ASEAN & ICH-GCG**  
(proposed in St.Louis –GCG meeting)

**Host** → National P’cal Control Bureau (NPCB)-Malaysia  
**Venue** → Kuala Lumpur, Malaysia  
**Trainers** → ICH-GCG

<table>
<thead>
<tr>
<th></th>
<th>MedDRA</th>
<th>Q5C</th>
<th>Q8-10</th>
</tr>
</thead>
</table>
| **Date**       | - 23-25Nov.09,  
                 - end of Jan.10, or  
                 early Feb.10 (?) | 3rd wk.of Jan.10(?) | 08-12 Mar. 2010 (?) |
<p>| <strong>ICH Coordinator</strong> | - Dr.Odette Morin | Dr.Spiros Vamvakas | Dr.Spiros Vamvakas |
| <strong>Participant</strong> | - Regulator &amp; Industries(+fee) / - Self-support |               |               |
| <strong>Type of Training</strong> | Regional Training | Regional Training | Regional Training |
| <strong>Status</strong>     | on-going     | on-going     | on-going      |</p>
<table>
<thead>
<tr>
<th></th>
<th>MedDRA</th>
<th>Q8-9-10</th>
<th>Q5C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date</strong></td>
<td>17-19 Mar.2010</td>
<td>26-28 Jul.2010</td>
<td>- Q4 FY 2010 (?)</td>
</tr>
<tr>
<td><strong>Contact point</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ICH</td>
<td>Dr.Odette Morin</td>
<td>Mr.Jacqueline MORENAS</td>
<td>Dr.Nick Gate</td>
</tr>
<tr>
<td>- ASEAN</td>
<td>Dr.Kamaruzaman SALEH</td>
<td>Mr.Muhammad L. IBRAHIM</td>
<td>Ms.Arpha ABAS</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(<a href="mailto:aarpah@bpfk.gov.my">aarpah@bpfk.gov.my</a>)</td>
</tr>
<tr>
<td><strong>Participant</strong></td>
<td>-22 regulators</td>
<td>- ...... regulators</td>
<td>- ...... regulators</td>
</tr>
<tr>
<td></td>
<td>-28 industries</td>
<td>- ...... industries</td>
<td>- ...... industries</td>
</tr>
<tr>
<td><strong>Type</strong></td>
<td>Regional Training</td>
<td>Regional Training</td>
<td>Regional Training</td>
</tr>
<tr>
<td><strong>Status</strong></td>
<td>Done</td>
<td>On-going</td>
<td>EMEA re-organization</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>In Tallinn:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><a href="mailto:peter.richardson@ema.europa.eu">peter.richardson@ema.europa.eu</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><a href="mailto:emer.cooke@ema.europa.eu">emer.cooke@ema.europa.eu</a></td>
</tr>
</tbody>
</table>

Yuppadee – 8 Jun 2010, Tallinn, Estonia
upcoming PPWG meeting
The 17th ACCSQ/PPWG Meeting

• **Indonesia**
  → week of July 19, 2010
  → main issues:-
    - new TOR of the PPWG
    - TOR of the MRA-GMP
    - MRA-BA/BE
    - the implementation
    - Q&A on ACTR & ACTD & Technical guidelines
    - ASEAN-International coop: *ICH-GCG, Vaccine Chapter*
    - Capacity Building
    - Variation guideline
    - the AEC
    - etc.
seminar
b/b with PPWG
The 18th ACCSQ/PPWG Meeting

- Thailand vs. any AMS (?)
  - date: Q1-Yr 2011 (?)
  - Seminar – 1 day prior to PPWG & related meetings
    - ICH Webinar
    - project of ICH-Regulator Forum: GCP(E6), GRP, Q7
    - WHO-pre Qualification programme (Pharmaceuticals)
    - WHO-GMP new guidelines
    - MedDRA
    - eCTD
    - Q4 series
    - ..........................................................
Recommendation to the GCG

→ note the update of the ASEAN-ACCSQ/PPWG
→ note the progress of ICH-GCG Training supported to ASEAN
  - pls. coordinate further for Q5C training

→ consider support Speakers for Seminar - 18th ACCSQ/PPWG
Thank You