ASEAN – Cooperation & Harmonization

by

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Outline:

• ASEAN Cooperation

• ASEAN Harmonization – the PPWG
ASEAN Cooperation
ASEAN

= Association of Southeast Asian Nations

Member

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

total population ~ 520 million
The ASEAN

- establishment → 8 August 1967
- population → ~ 520 mil.
- area → 4.5 mil.Km²
- combined gross domestic product → 750 mil.USD
- total trade → 720 mil.USD
The ASEAN (1)

- **Objective:**
  (i) accelerate the economic growth, social progress, and cultural development
  (ii) 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

- ASEAN Summit
- AEM → HLTF
- SEOM
- ACCSQ

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

PWGs
- ACC (ASEAN Committee on Cosmetic)
- PPWG (Pharmaceutical PWG)
- EE PWG (Electrical and Electronic PWG)
- PI PWG (Prepared Foodstuff PWG)
- TMHS PPWG (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 $\rightarrow$ 1992
- purposed $\rightarrow$ to enhance Economic Cooperation
- strategic objective $\rightarrow$
  
  “To increase the ASEAN region’s competitive advantage as a single production unit”

- target function $\rightarrow$ tariff, TBT, and NTB
The ASEAN (7) – the AEC (i)

- the 9th ASEAN Summit :
  -> on 7 Oct. 03
  -> signed the *Bali Concord II*
  -> mandated timeline for AEC to be by the year 2020
  -> 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 ASEAN (10) – the HLTF (i)

- establishment ➔ by AEM in 2002
- the works ➔ Recommendations (adopted by AEM & Summit)
- scope ➔ work on 11+1 Priority products

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Pharmaceutical ➔ Healthcare sector
The ASEAN (11) – the HLTF (ii)

- major recommendations → on Pharmaceuticals
  - study the feasibility of MRA
  - formalization of a Post-marketing Alert System
  - harmonize a Labeling Std.&Requirement
  - explore the feasibility a flexible Twining System
  - implement ACTD (by 31 Dec. 08)
  - explore the feasibility of adopting a Harmonized Placement system
    (after ACTD Implementation)
ASEAN Harmonization

The PPWG
The PPWG (1) – Full name

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** ACCSQ → endorsed “2nd & 3rd 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”
**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!
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)
The PPWG (8) – Agreement

1. Harmonized Key Areas → agreed!
2. Format for ACTR & ACTD → agreed!
3. Content of ACTR / ACTD / Glossary of Term → agreed!
4. ASEAN Harmonized Products → completed!
5. Implementation -Trial period → Sep. 2003 onwards
The PPWG (9) – Working Scheme

Comparative study
on Registration Requirement & Regulation

Identification the “Key Area on Requirements”
for Harmonization

Assignment “Lead Countries”

“The Lead Countries” Working

Member countries

The Meeting

Agreement
“ASEAN Harmonized Product”

Endorsement
(ACCSQ / SEOM / AEM /…)

Implementation
by Members
The Ultimate Goal of ASEAN

ASEAN Economic Community (AEC)
“by the year 2020..... 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

AEC ➔ year 2015
Thank You