



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 :**
 - (i) **Mutual respect for the independence, sovereignty, equality territorial integrity, and national identity of all nations**
 - (ii) **The right to lead its national existence free from external interference, subversion, or coercion**
 - (iii) **Non-interference in the internal affairs of one another**
 - (iv) **Settlement of differences or disputes by peaceful manner**
 - (v) **Renunciation of the treat or use of force,**
 - (vi) **Effective cooperation among themselves**



The ASEAN (3)

- **Structure and Mechanisms**



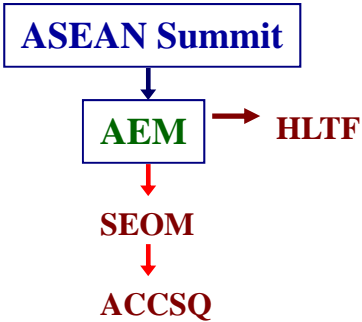


The ASEAN (4) - Major Cooperation





The ASEAN (5) – Economic Cooperation



WGs

- WG1 on Mutual Recognition Arrangements (MRAs) & Standards –
- WG2 on 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)
- Pf 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 → 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 (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*

-Wood-based	-Rubber-based	- Electronics
- Automotives	- Textiles&Apparels	- Air travel
- <u>Healthcare</u>	- Agro-based	- Tourism
- e-ASEAN	- Fisheries	- <i>Logistics</i>

***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 Twinning 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*)

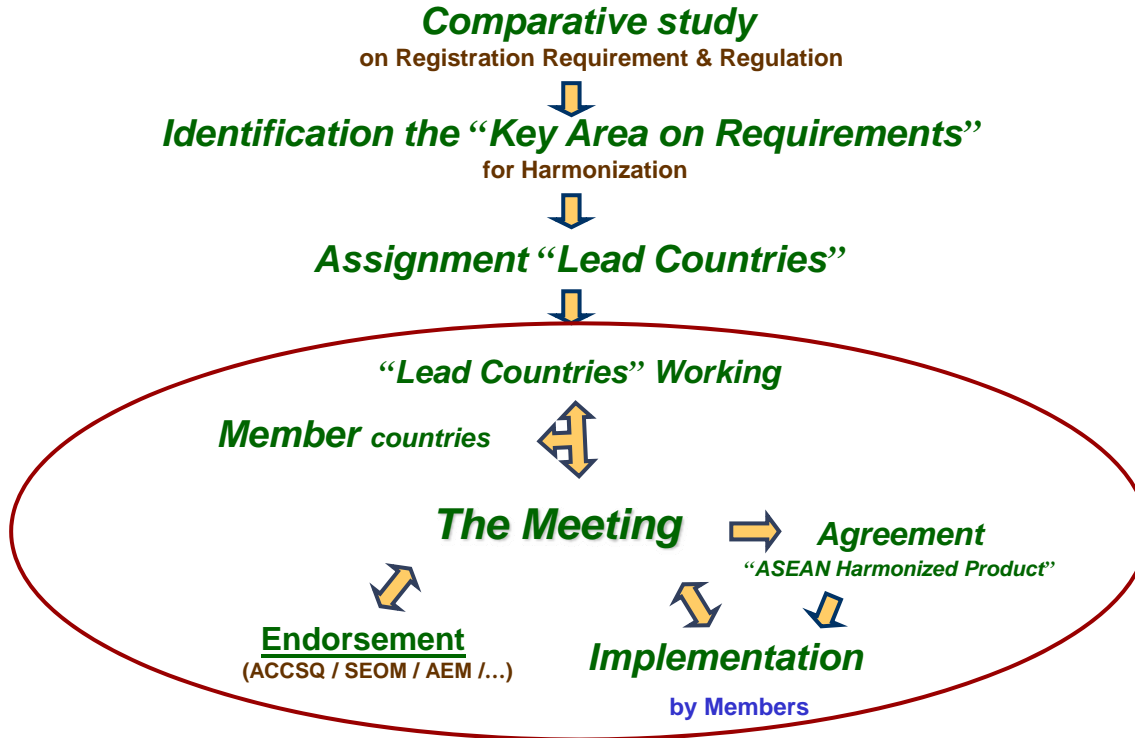


The PPWG (8) – Agreement

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*
6. Full Implementation → *by 31 Dec. 2008*



The PPWG (9) – Working Scheme





The Ultimate Goal of ASEAN

ASEAN Leader Summit



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

