



ASEAN PPWG

Regional Update on ICH-related Matters

by

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The ICH-Global Cooperation Group Meeting

Sokos Viru Hotel, Tallinn, Estonia

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Topics

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

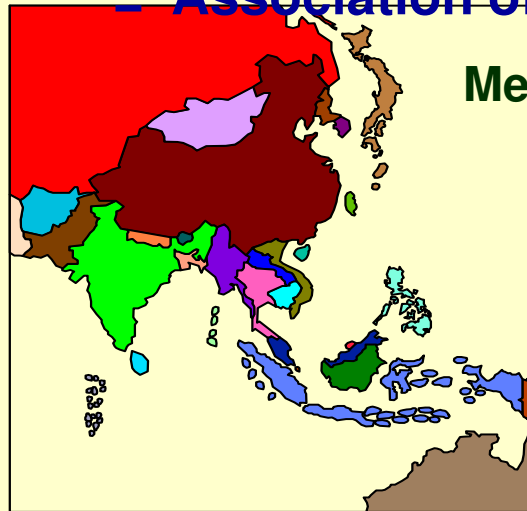


The ASEAN



ASEAN

= Association of Southeast Asian Nations



Member

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

total population ~ 580 million



ASEAN-PPWG



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 :**
 - (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**



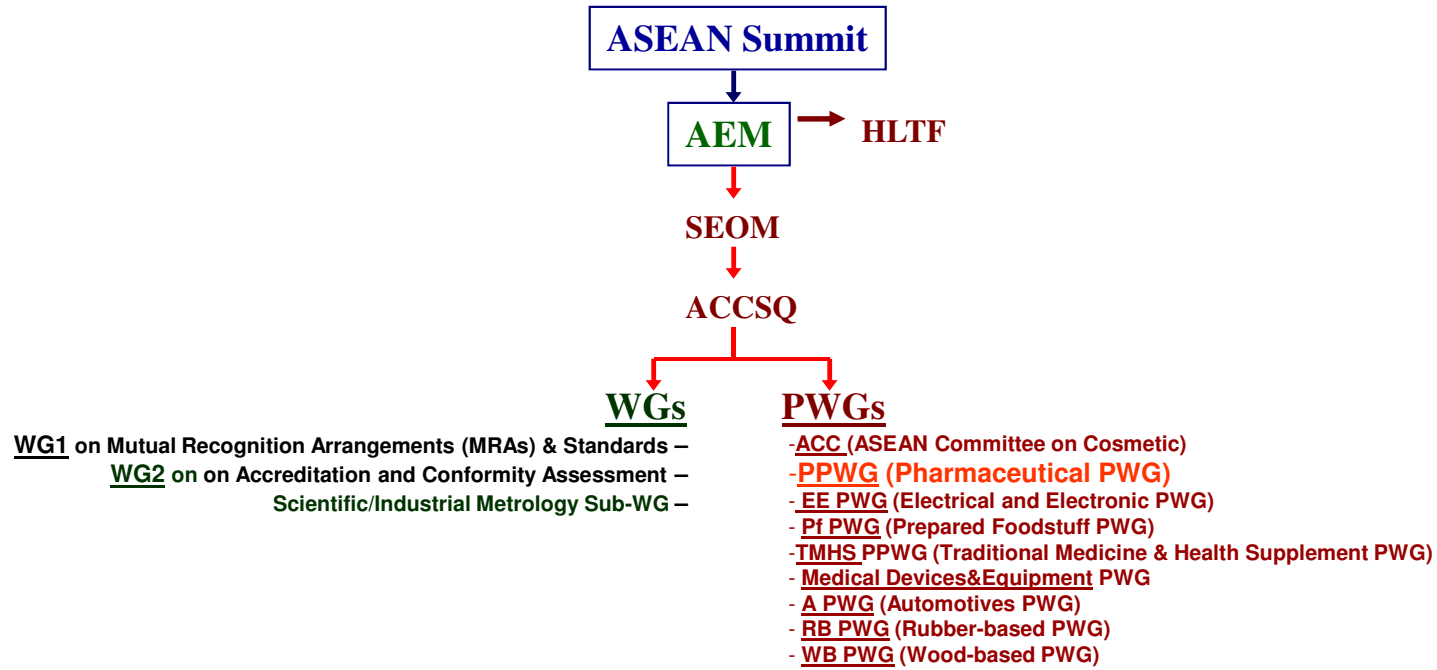


The ASEAN (4) - Major Cooperation





The ASEAN (5) – Economic Cooperation





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 Leader Summit



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



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

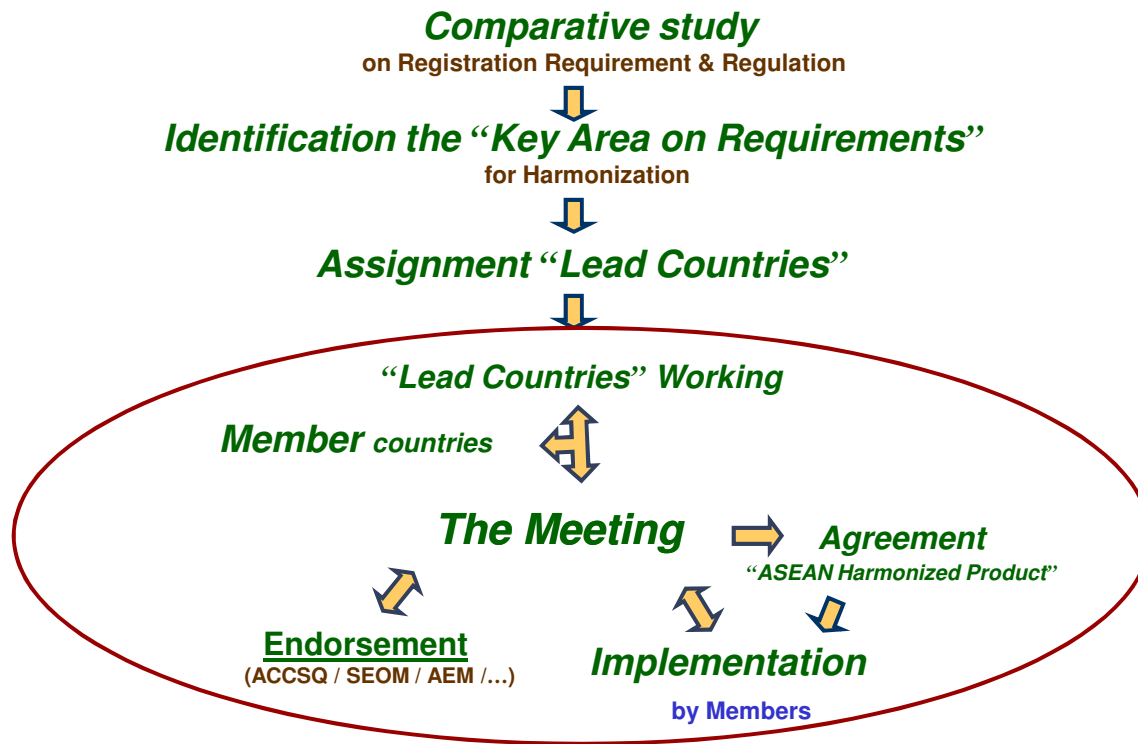


The PPWG (8) – Agreement

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





ACTR

*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*

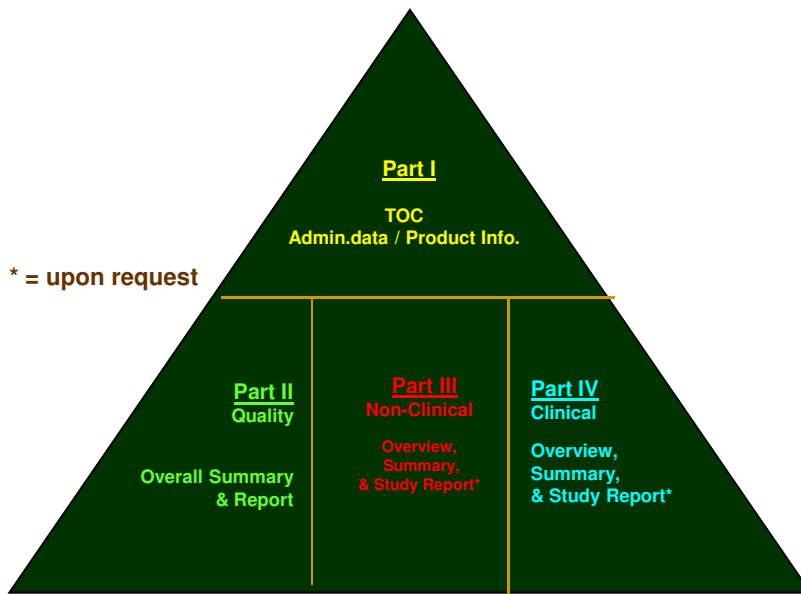


ACTD

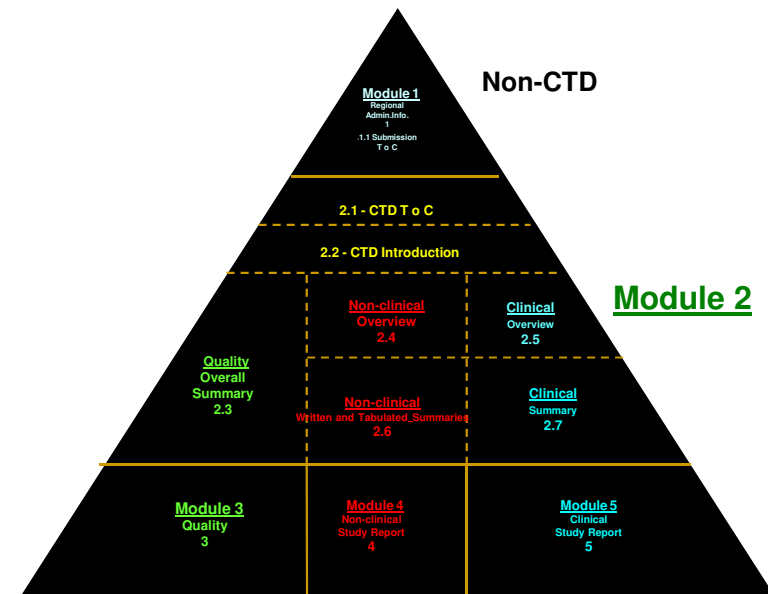
**The part of
marketing authorization application dossier
that is common to
all ASEAN member countries**



ACTD



ICH-CTD





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*

	MedDRA	Q5C	Q8-10
• Date	- 23-25Nov.09, - end of Jan.10, <u>or</u> early Feb.10 (?)	3 rd wk.of Jan.10(?)	08-12 Mar. 2010 (?)
• ICH Coordinator	- Dr.Odette Morin	Dr.Spiros Vamvakas	Dr.Spiros Vamvakas
• Participant	- Regulator & Industries(+fee) / - Self-support 		
• Type of Training	Regional Training	Regional Training	Regional Training
• Status	on-going	on-going	on-going



ASEAN Activities :- ASEAN & ICH-GCG

The Update

	MedDRA	Q8-9-10	Q5C
• Date	17-19 Mar.2010	26-28 Jul.2010	- Q4 FY 2010 (?)
• Contact point - ICH -ASEAN	-Dr.Odette Morin - Dr.Kamaruzaman SALEH	-Mr.Jacque MORENAS -Mr.Muhammad L. IBRAHIM	-Dr.Nick Gate -Ms.Arpah ABAS (aarpah@bpfk.gov.my)
• Participant	-22 regulators -28 industries	-.....regulators -..... industries	-.....regulators -..... industries
• Type	Regional Training	Regional Training	Regional Training
• Status	Done	On-going	EMEA re-organization <u>In Tallinn:-</u> <peter.richardson@ema.europa.eu> <emer.cooke@ema.europa.eu>



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
 -

Proposal / Suggestion ?



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

