

# **ASEAN**

## **Regulatory Harmonization Scheme Overview & Pharmaceuticals Regulatory Harmonization Update**

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**“The 10<sup>th</sup> WSMI & 2<sup>nd</sup> APSMI”**  
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# The ASEAN





# ASEAN = Association of Southeast Asian Nations





**Old members = ASEAN 6**

**New members= CLMV**











## ASEAN Economic Community



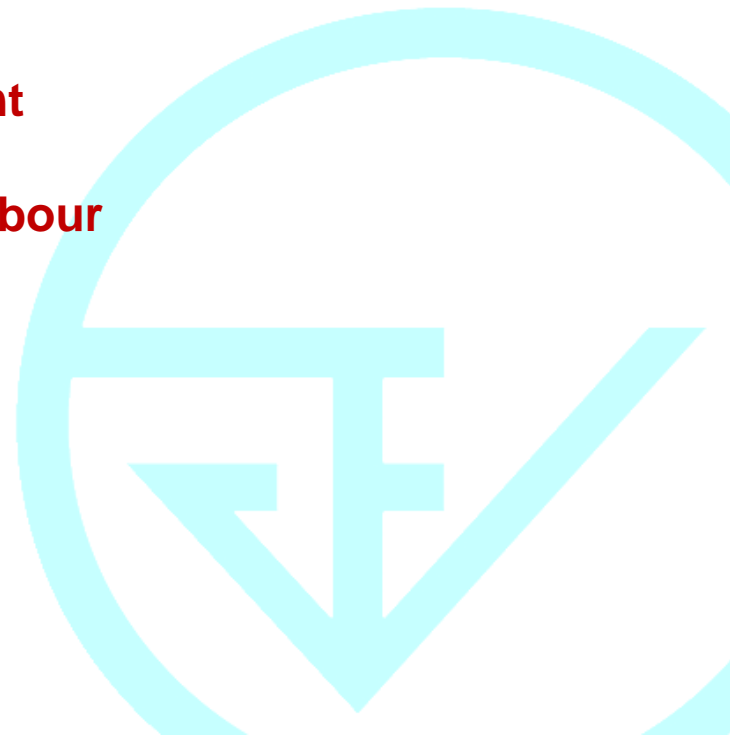
# The Goal on Economic

## 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 AEC

**Aim → 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*

**AFTA = ASEAN Free Trade Area**

**AFAS = ASEAN Framework Agreement on Services**

**AIA = ASEAN Investment Area**





## **AEC – the Measures/Mandates...**

**ASEAN Charter**  
**AEC Blueprint**  
**AEC Scorecard**  
**ASEAN Good Regulatory Practice (GRP)**  
**ASEAN Trade Facilitation Work Programme**  
**ASEAN Trade in Goods Agreement (ATIGA)**

### **Establishment .....**

- 1. Legal unit**
- 2. ACB (ASEAN Compliance Body)**
- 3. ACT (ASEAN Consultation to Solve Trade and Investment Issues)**





# Leader's Mandate

to accelerate ASEAN Harmonization  
towards AEC

for 12 Priority Products



- **Healthcare**
- Agro-based products
- Air traveling
- Automotive
- e-ASEAN sectors
- Electronic & Electric Equip.
- Fisheries
- Logistics
- Textiles and apparels
- Tourism
- Rubber-based products
- Wood-based product



## 1. Single “Market & Production Base”

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

## 2. High Competitive Economic Region

- e-ASEAN
- tax & tariff
- competitiveness
- IPR
- Consumer protection
- Infrastructure Development



**2015**

## 3. Equitable Economic Development

- bridging “Old & New Members”
- SMEs

## 4. Fully integrated into Global Economy

- FTAs with Non-ASEAN
- enhance Economic Cooperation



# 2015

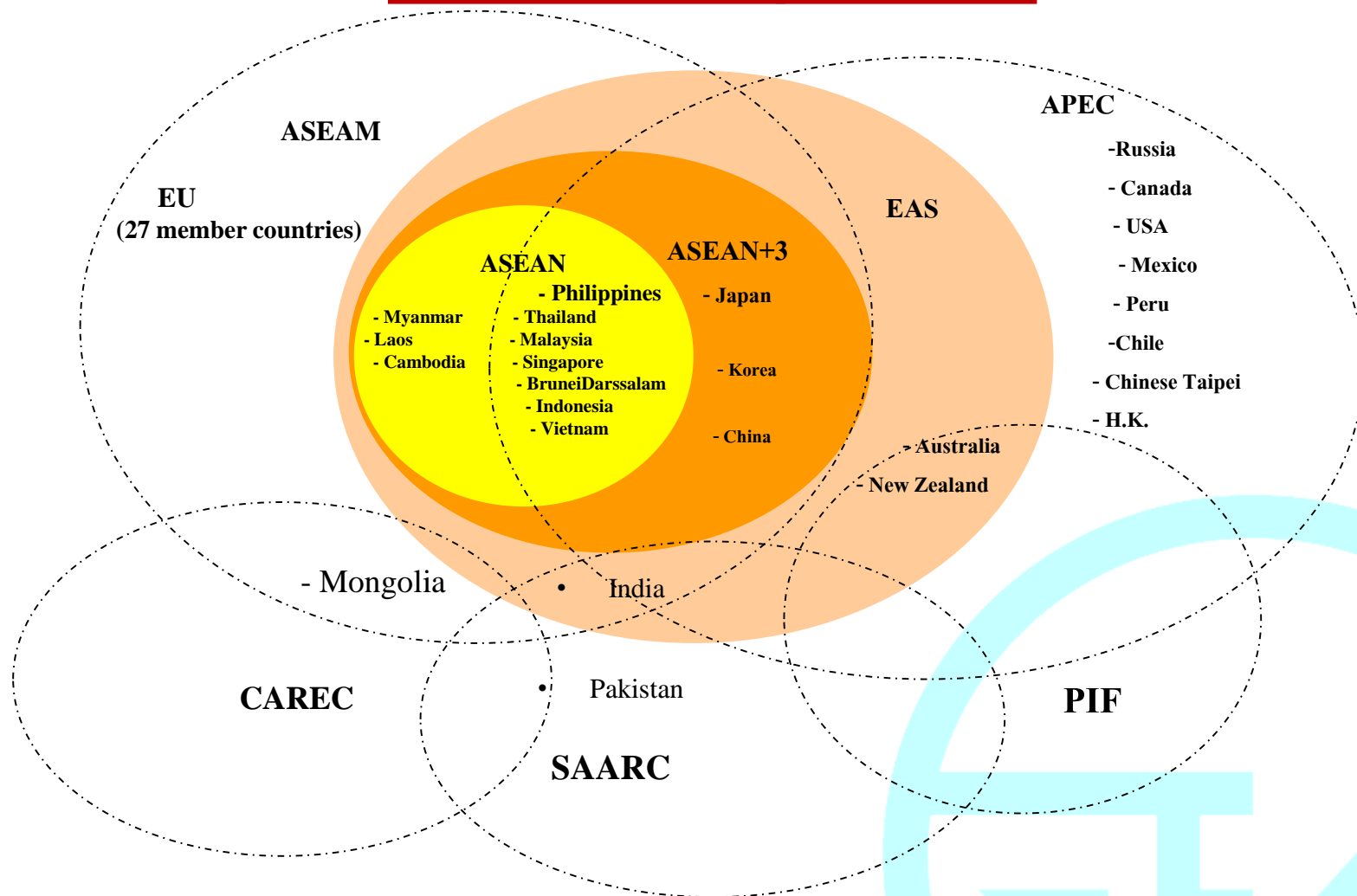
Goods	<ul style="list-style-type: none"> <li>• <b>Tariff = 0</b></li> <li>• <b>no barrier in importing w/in ASEAN</b></li> <li>• <b>10 Markets → 1 Single market</b></li> </ul>
Services	Free flow
Investment	Free flow
Skilled Labour	Free flow (engineering, architecture, physician, dentist, nursing, accountancy, survey, tourism)
Capital	Free flow

# ASEAN's International Cooperation





# ASEAN Cooperation



**ASEAM = Asia-Europe Meeting**

**EAS = East Asia Summit**



# 5 FTAs of “ASEAN & Partners”



## AJCEP

\* **Goods / Services /  
Investment**



## AANZFTA

\* **Goods / Services /  
Investment**



## ACFTA

**Goods/ Services / Investment**



## AIFTA

\* **Goods**  
\* **Services/ Investment**  
- negotiating



## AKFTA

**Goods / Services / Investment**

AJCEP = ASEAN-Japan

ASEAN-Japan Comprehensive  
Economic Partnership Agreement





## แต่ยังต้อง “เร่งสร้าง” ศักยภาพรองรับ AEC



...โดยภาครัฐต้องเร่งปรับปรุงและพัฒนา...

โครงสร้างพื้นฐานทางกายภาพของท่าอากาศยาน...  
ไม่เว้นเวย์...อาคารผู้โดยสาร...และสิ่งอำนวยความสะดวก  
ต่อผู้โดยสาร และสายการบิน ควบคู่กับการเพิ่มประสิทธิภาพ  
และคุณภาพของระบบการให้บริการ เพื่อให้มีขีดความสามารถ  
รองรับการเพิ่มขึ้นของเที่ยวบินผู้โดยสารและสินค้า...  
ได้อย่างมีประสิทธิภาพสูงสุด นอกจากนี้ สิ่งสำคัญคือ...  
การสร้างเครือข่ายเชื่อมโยง (Connectivity) กับประเทศอื่นๆ  
ในภูมิภาค "เพื่อจูงใจ" ให้สายการบินจากนานาประเทศ...  
เลือกใช้ “ไทย” เป็นจุดหมายปลายทาง...







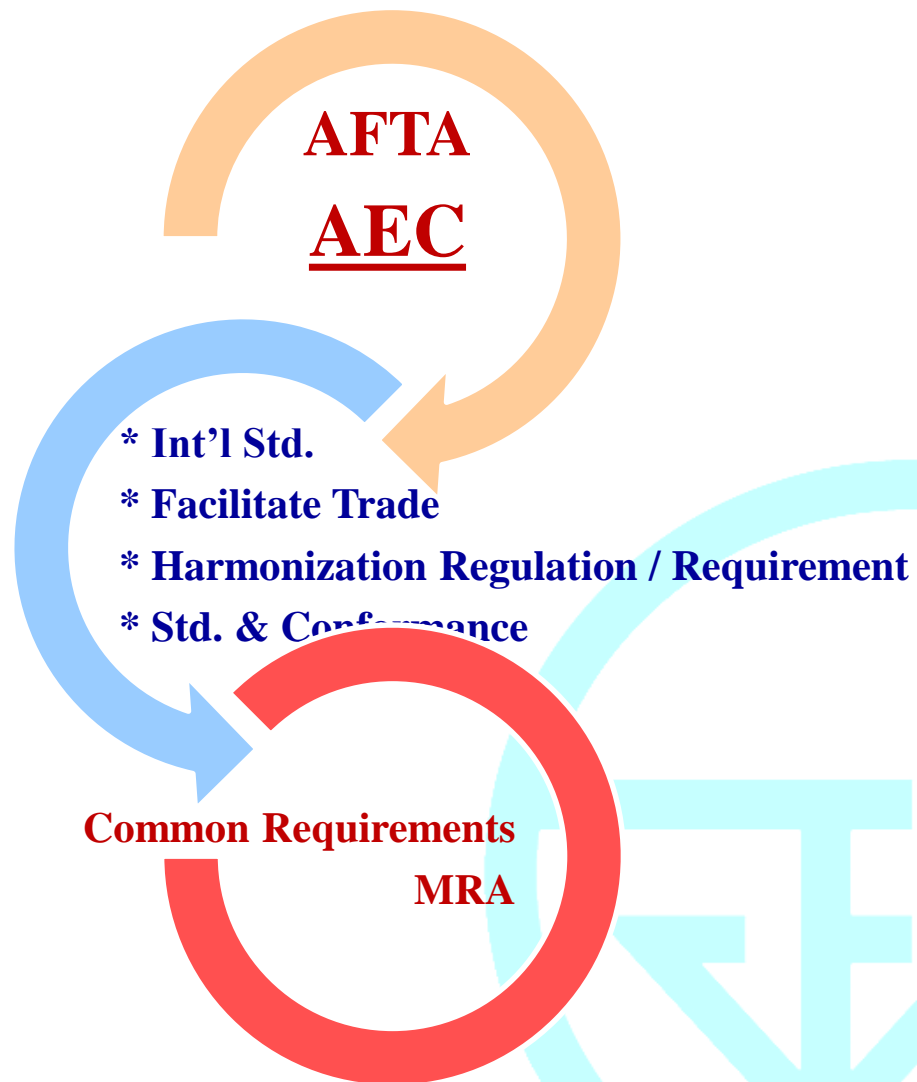


# ASEAN

## Regulatory Harmonization Scheme Overview



# ASEAN Leaders “MANDATES”





# The ASEAN- Cooperation

## ASEAN Summit

### Economic Cooperation (AEC)

AEM  
SEOM  
ACCSQ

WG1 - Mutual Recognition Arrangements (MRAs) & Standards

WG2 - Accreditation and Conformity Assessment

WG3 - Scientific/Industrial Metrology

ACC - ASEAN Committee on Cosmetic

**PPWG - Pharmaceuticals PWG**

Pf PWG - Prepared Foodstuff PWG

TMHS PWG - Traditional Medicine & Health Supplement PWG

Medical Devices&Equipment PWG

EE PWG- Electrical and Electronic PWG

A PWG - Automotives PWG

RB PWG - Rubber-based PWG

.....

- Political & Security Cooperation (APSC)

- Socio-cultural Cooperation (ASCC)

AHMM  
ASCC Council  
ASOD  
SOMHD

**AWGPD** – ASEAN Working Gr. on Pharmaceuticals Dev.

ASEAN Sectoral Working on Traditional Medicine  
Initiatives on Traditional Medicine

**ThaiFDA → involvement in ASEAN**

# **ThaiFDA & PWG**

## **Regulatory Harmonization**

<b><u>Year</u></b>	<b><u>Product</u></b>
--------------------	-----------------------

<b>1997 →</b>	<b>Cosmetic</b>
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<b>1999 →</b>	<b>Pharmaceuticals</b>
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<b>2001 →</b>	<b>Prepared Food Stuff</b>
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<b>2004 →</b>	<b>(1) Traditional Med. &amp; Health Supplement</b>
	<b>(2) Medical Devices</b>



# ASEAN

## Pharmaceuticals Regulatory Harmonization Update





## PPWG → ACCSQ/PPWG

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

### **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 !!!!**



## Pharmaceuticals PWG (PPWG)

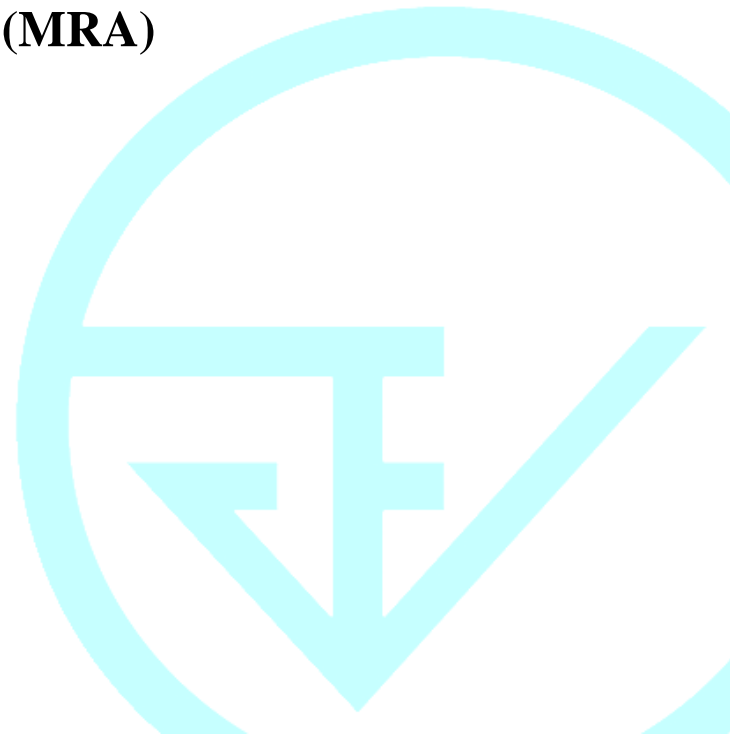
**Principle** → to promote “Registration”, “Trade”, & “Co-operation”

→ to eliminate “TBT”

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

**Output** → ASEAN Harmonized Product (*ACTR, ACTD, guidelines*)

→ Mutual Recognition Agreement (MRA)





# **The PPWG – *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 & 2011 & 2014**

**ACCSQ → endorsed “2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> & 5<sup>th</sup> & 6<sup>th</sup> Term of the PPWG”**  
**(same Chair & Co-Chair countries)**



# **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 /Efficacy* → Thailand
- **IWG : Singapore / Indonesia ( (*Chair & Co-Chair*)**
- **MRA-GMP : Singapore / Malaysia (*Chair & Co-Chairs*)**
- **MRA-BA/BE: Indonesia / Malaysia (*Chair & Co-Chairs*)**
- **Post-marketing Alert System (PMAS): Singapore / Malaysia**
- **Biologics coop. → Indonesia / Singapore**
- **Variation guideline → Malaysia**





## **ACTR**

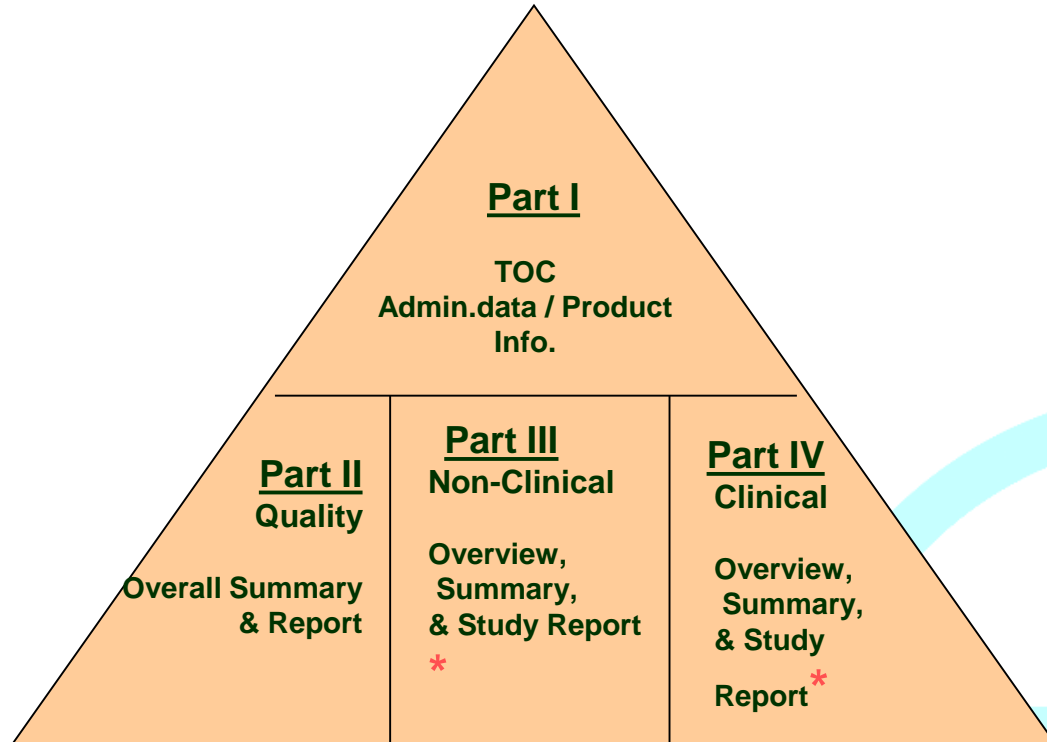
*A set of Written Materials  
intended to guide applicants  
to prepare application dossiers  
in a way that is consistent with the expectations  
of  
all ASEAN Drug Regulatory Authorities*

## **ACTD**

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



# Format of ACTD



\* = upon request

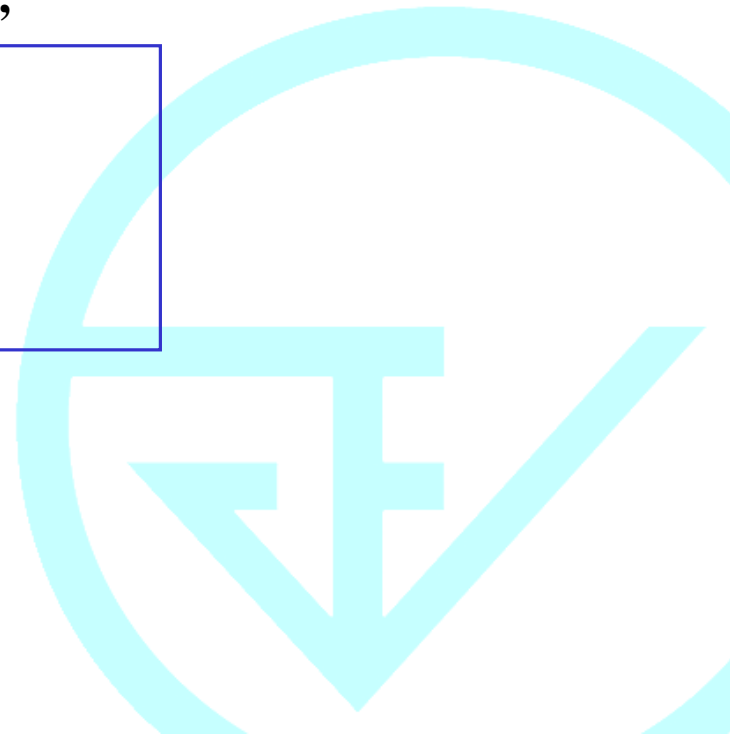




# **ACTR, ACTD, Technical guidelines**

- **ACTR** (ASEAN Common Technical Requirement)
- **ACTD** (ASEAN Common Technical Dossier)
- **Technical “Quality, Safety, Efficacy” guidelines -**
  - adopted guidelines (from WHO, ICH, and International pharmacopoeia)
  - newly developed ASEAN Quality guidelines;

- (1) **Analytical Validation guideline**
- (2) **BA/BE Studies guideline**
- (3) **Process Validation guideline**
- (4) **Stability Study guideline**





# S&E Technical guideline

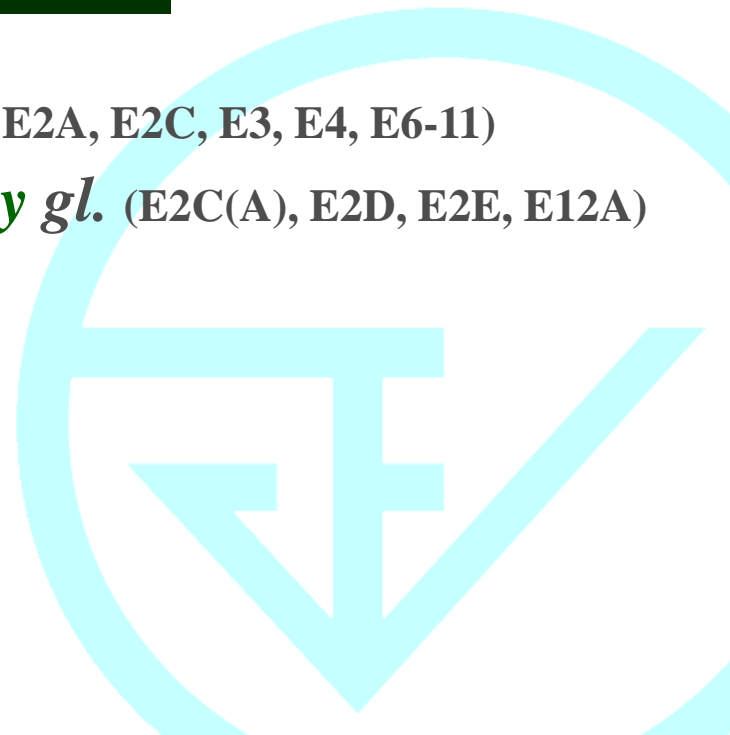
## Guideline - *Safety*

→ adopted 15 *ICH-Safety gl.*

## Guideline - *Efficacy*

→ adopted 11 *ICH-Efficacy gl.* (E1, E2A, E2C, E3, E4, E6-11)

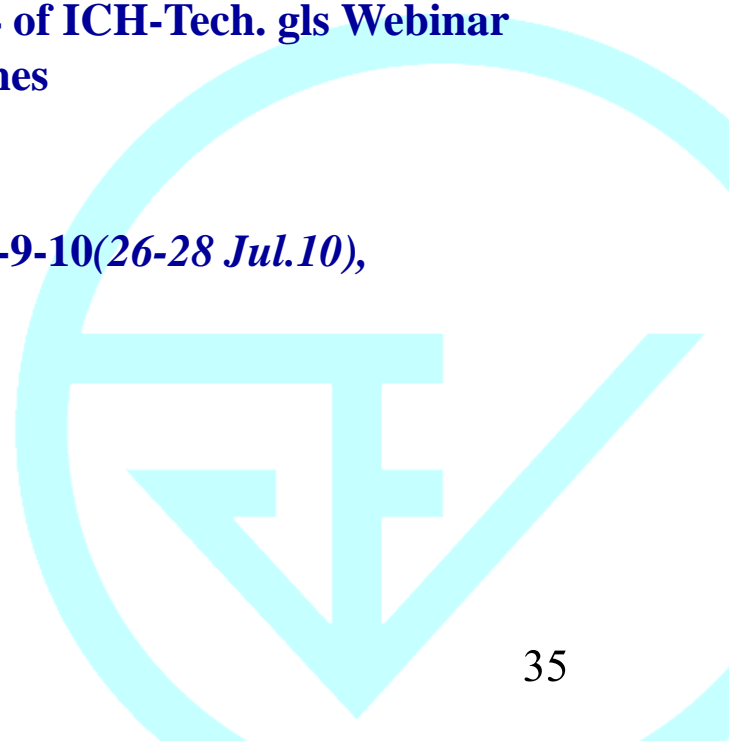
→ accepted as Ref.gl. 4 *ICH-Efficacy gl.* (E2C(A), E2D, E2E, E12A)





# Cooperation “PPWG & ICH” – the GCG

- **started from ICH 6 (Yr 2003)**
- **invited by ICH to the ICH-GCG Meeting.**
  - The PPWG decided to attend as an Observer, and assigned Co-Chair to be the Rep. since May 2004.
- **Main cooperation;**
  - sharing info. / updating progress
  - providing comment & participating on Step 2 & 4 of ICH-Tech. gls Webinar
  - utilization and adoption of ICH Technical guidelines
  - training supports (Speakers)
- **the past Training supports (Yr.2009-11);**
  - on Training project: MedDRA(23-25 Nov.09), Q8-9-10(26-28 Jul.10), and Q5C(30-31 May 2011)





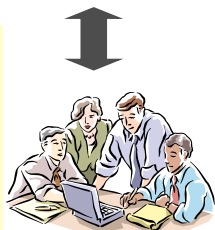
## Working Scheme of the PPWG

### Agreement

- ACTR, ACTD, Technical guidelines
- Full implementation timeline
- ASEAN Sectoral MRA on GMP Inspection
- Variation guideline

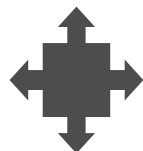
the Works - "Lead Countries"/Members

- Tech. discussion gr.
- Dialogue w/ Association
  - IWG
- MRA Task forces /JSC
  - HOD
  - PPWG



### the Meetings

Endorsement  
(ACCSQ / SEOM / AEM  
/...)



Agreement  
(ASEAN Har  
MRAs)

Implementation  
Capacity Building/Strengthening

## Activities of PPWG (Pharmaceuticals)

### (1) Implementing ASEAN Har.products

- for new application
- for existing Drug license (by 2012)

### (2) Processing of the GMP-MRA JSC

### (3) BA/BE MRA

### (4) Updating Tech.gls.

### (5) Harmonizing Biological , Biotech., Biosimilar product

### (6) Facilitating the AEC

### (7) Coop.with international forum: ICH, WHO, etc.



# **Recent Update of the ASEAN PPWG**

## **MRA-GMP**

- **3 Listed Inspectorate Units (PIC/S Membership:- *Singapore, Malaysia, Indonesia*)**
- **1 new , to be, Listed Inspectorate Unit (Thailand)**
- **1 more Liste Inspectorate Unit, by the end of 2015**

## **MRA-BA/BE Study Report**

- **Aiming to be ready by Dec.2015**
- **Under “ASEAN-EU” support, now**
- **Workshop & Training, in Nov.2014**

## **Harmonization on Biologic**

- **On going**
- **Working with WHO, for technical support**

## **The Next Meeting**

- **March 2015 in LaoPDR**



# **The PPWG– Recognition & Agreement**

- to facilitate AFTA & AEC
- to eliminate Technical Barrier to Trade (TBT)
- to align to International Standards
- **without compromising on Quality, Safety, Efficacy of Pharmaceuticals**

**Product License**



***the Decision***  
**of individual Member Country**

# ASEAN Technical Cooperation – ASCC(1)



## Pharmaceutical care

## Health/P'cals Policy

### Current Programme

- \* Programme of Good Manufacturing Practices [Id]
- \* Standardization, Quality Control and Validation of Herbal Medicine [Id & Th]
- \* Programme to Promote Rational Drug Use [Bn & Sg]
- \* Collaborating Center for the Production of ASEAN Reference Substances [Th-DMSc]
- \* Programme for Drug Evaluation [Ph]
- \* **Building up and Strengthening ASEAN's Capacity in GCP and Clinical Trials [Th-ThaiFDA]**
- \* ASEAN Collaboration in Combating Counterfeit Drug [Id]
- \* Building up and Strengthening of Pharmacovigilance System in ASEAN [Sg]

### Additional Cooperation Topics with Others

- Rational Use of Medicine [WHO-RO]
- Drug Resistance in Malaria/ Replacement of Artemisinin base monotherapy by Artemisinin Combination Therapy (ACT) [ASEC/WHO-RO]

# Leading Role of ThaiFDA in AWGPD

ASEAN Summit

AFTA

## Work done:

1. Finalization of AWGPD-TOR new format
2. Questionnaire survey
3. The 1<sup>st</sup> Workshop (Joint with MRCT WS) –SOM II (May 2014)

## Next Steps:- ...

- \* Cooperation work with APEC-GCP Inspection
- \* Cooperation with Japan, via APEC-MRCT)
- \* Develop & conduct the Training !

Political & Security Cooperation  
Socio-cultural Cooperation - ASCC

AHMM, ASCC Council, ASOD  
SOMHD  
AWGPD

Programme of Good Manufacturing Practices [Id]

Standardization, Quality Control and Validation of Herbal Medicine [Id & Th]

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