Transparency and Interaction with Regulatory Authorities

Yuwadee Patanawong

Food and Drug Administration,Thailand

8 November 2012

THAILAND

POPULATIONS 67 Million 77 PROVINCES Area 513,115.02 km^2

ASEAN Pharmaceutical/Medical Device Harmonization

- We do not talk about Good Review Practice.

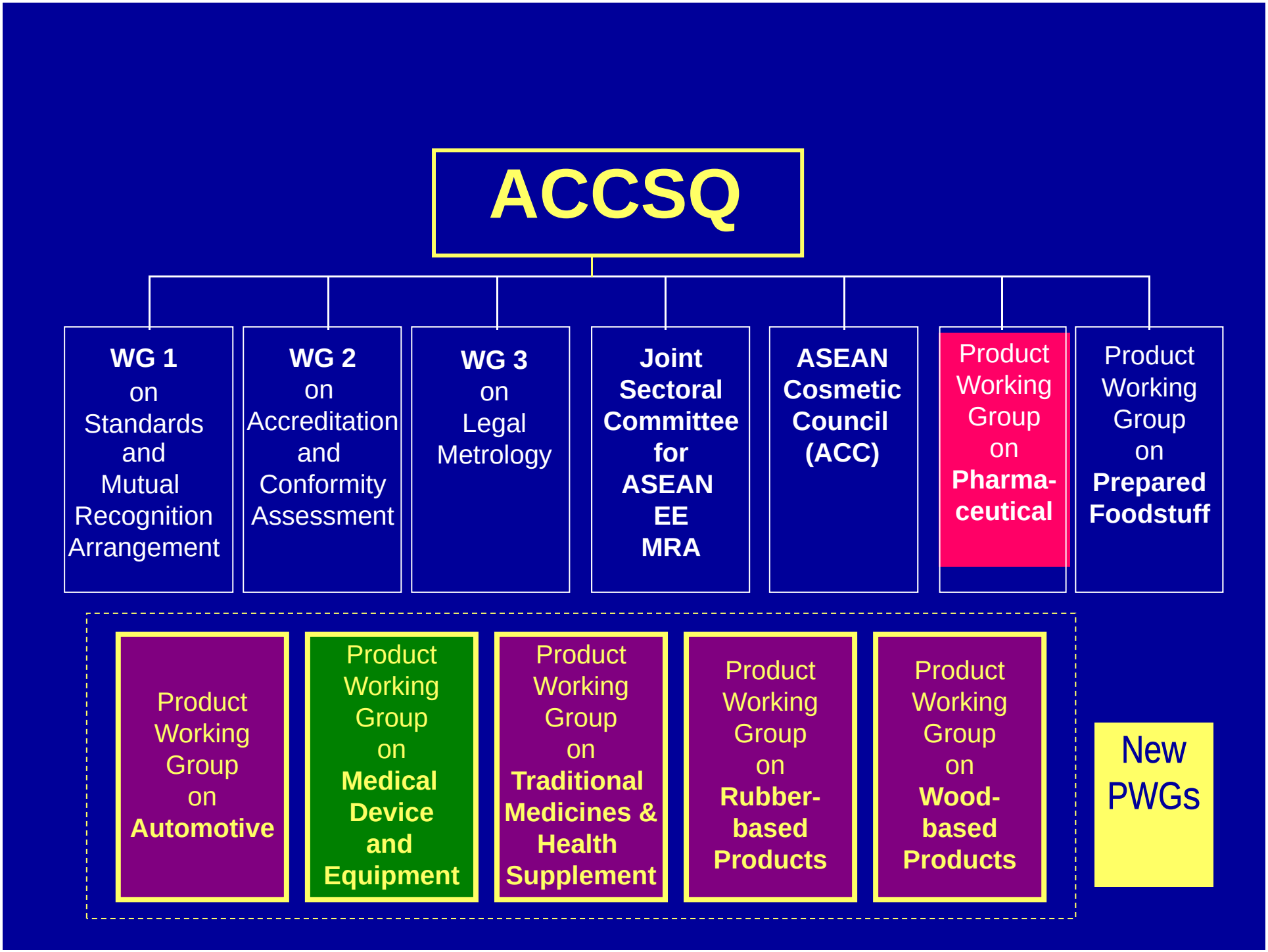
- We have ASEAN Good Regulatory Practice (GRP) Guide (Endorsed by SEOM Meeting 2-4 Feb 2009)

ASEAN (Association of Southeast Asian Nations) established on 8 August 1967

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

Population 600 million people

ASEAN Structure


ACCSQ
WG 1 on Standards and Mutual Recognition Arrangement
WG 2 on Accreditation and Conformity Assessment
WG 3 on Legal Metrology
Joint Sectoral Committee for ASEAN EE MRA
ASEAN Cosmetic Council (ACC)
Product Working Group on Pharma-ceutical
Product Working Group on Prepared Foodstuff
Product Working Group on Automotive
Product Working Group on Medical Device and Equipment
Product Working Group on Traditional Medicines & Health Supplement
Product Working Group on Rubber-based Products
Product Working Group on Wood-based Products
New PWGs

Decision Making of ASEAN Pharmaceutical/Medical Device Harmonization

Must always be Consensus basis

Objectives of ASEAN Good Regulatory Practice (GRP) Guide

- to provide similar approaches to regulatory management within ASEAN in the preparation, compliance to and review of technical regulations

- to assist regulators in ASEAN Member States in the adoption of efficient regulatory arrangements which should improve the consistency and transparency of technical regulations, thereby leading to reduction in regulatory barriers to trade

Specific Tools for Enabling ASEAN GRP

- Use of Regulatory Impact Assessment (RIA) to ensure that the proposed regulation is assessed for its need and net impact on society

- The results of this analysis are detailed in the Regulatory Impact Statement (RIS)

Series of Steps for RIA

1. Defining the problem
2. Setting objectives
3. Assessing all feasible options
4. Analysing the impacts arising from these options and
5. Consulting with stakeholders

Key Elements for RIS

1. The problem which give rise to the need for action
2. The desired objectives
3. The options (regulatory and non-regulatory)
4. An assessment of the impact (costs and benefits) on consumers, business, government and the community of each option, including the impact on small business paperwork and compliance costs
5. A consultation statement (process and results)
6. A recommended option
7. A strategy to implement

Output from ASEAN Harmonization on Pharmaceutical Products

- First PPWG Meeting in 1999
- 19th PPWG Meeting 2-6 July 2012

1. ASEAN Common Technical Dossier (ACTD)
2. ASEAN Common Technical Requirements (ACTR)
3. Guidelines e.g. Bioavailability & BE Studies, Stability Study, Process validation, Validation of analytical procedures
4. ASEAN sectoral mutual recognition agreement on GMP Inspection of Member States

Output from ASEAN Harmonization on Medical Devices (1)

- First MDPWG Meeting in 2005
- 16th MDPWG Meeting 10-11 October 2012

1. ASEAN Agreement on Medical Device Directive (AMDD) to be finalized

Important contents of AMDD:

- Definition of Medical Devices
- Classification of Medical Devices (MD non IVD and IVD)
- ASEAN Common Submission Dossier Template (CSDT)
- Essential Principles of Safety and Performance of Medical Devices

Output from ASEAN Harmonization on Medical Devices (2)

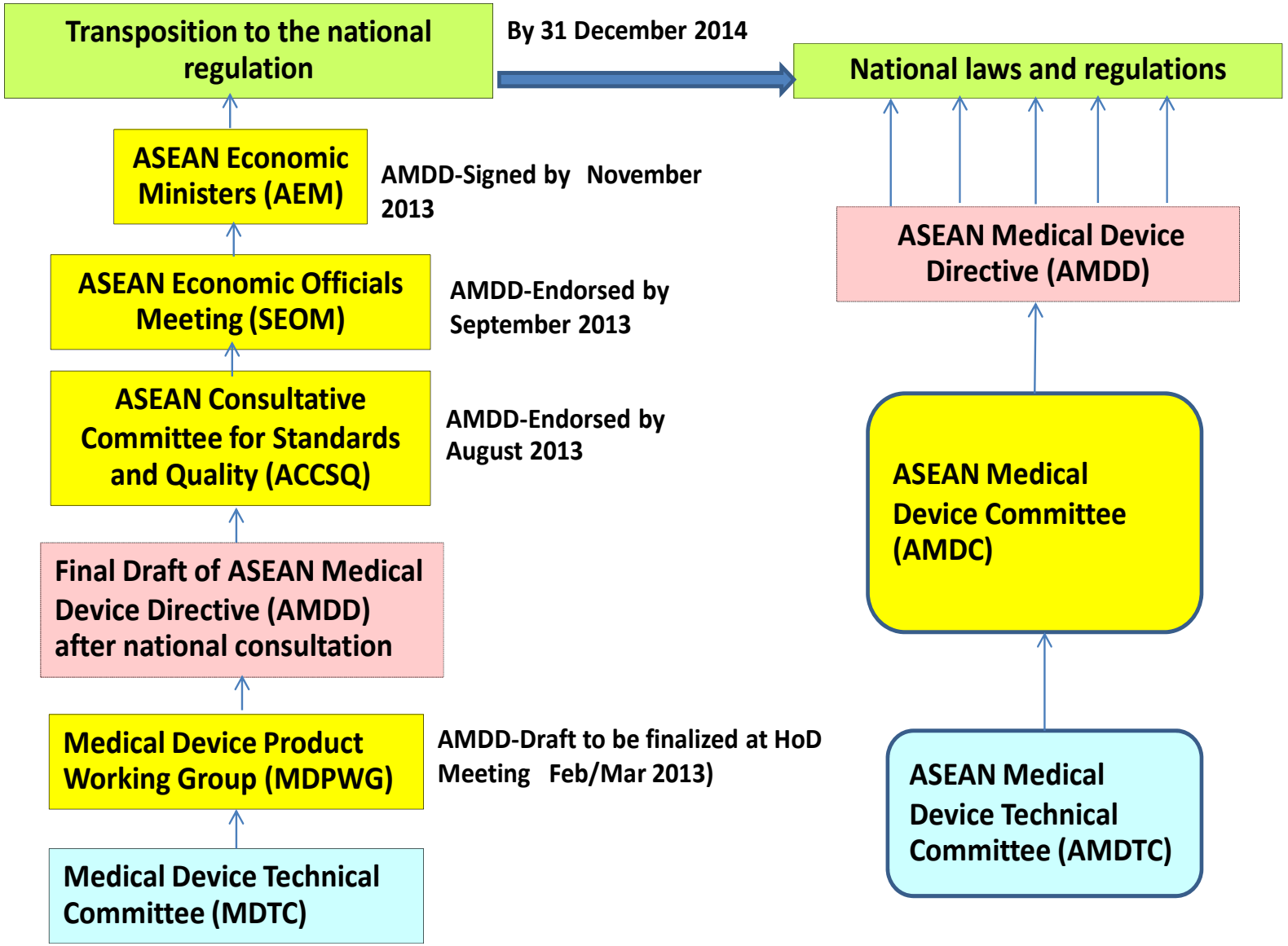
Important contents of AMDD : (continued)

- Post Marketing Alerts System (PMAS) Requirements
- Component Elements of a “Dear Healthcare Professional” Letter
- Labelling requirement
- Reference to Standards and Relevant Documents
- Clinical investigation
- ASEAN Medical Device Committee (AMDC)
- ASEAN Medical Device Technical Committee (AMDTC)

Output from ASEAN Harmonization on Medical Devices (3)

2. Guideline for CSDT Implementation
3. Guideline for Medical Device Classification
4. Agreement on Sharing Confidential Information relating to Adverse Events associated with medical devices among ASEAN Member States to be finalized

ASEAN Roadmap for Implementation of ASEAN Agreement on Medical Device Directive



GRP in Thailand

- In 2009, started the Quality Management System to enhance implementation of technical regulations in accordance with ASEAN GRP
- Educating FDA personnel
- Situation Gap analysis
- Put GRP as one of action plan

Quality Management System in Thai FDA

- Quality system Policy
- Quality System Documentation –Document and Data Control
- Quality System Standard – General Requirements for Thai FDA

Adapted from ISO/IEC Guide 62:1996 (ISO/IEC 17021:2006) General requirements for bodies operating assessment and certification/registration of quality systems and

ISO/IEC Guide 65:1996 (ISO/IEC 17065:2012) General requirements for bodies operating product certification systems

Notice for Good Review Practice (GRevP):Transparency & Interaction with Regulatory Authorities (1)

- Drugs vs Medical Devices

Medical Device - more varieties/numbers

- more standards to be considered

- faster technology change

- existing 3rd party reviewer

We need appropiate GRevP Templates & Guidelines: General & Some specific ones to help for transparent, consistent and efficient review

Notice for Good Review Practice (GRevP):Transparency & Interaction with Regulatory Authorities (2)

- GRevP approach between Internal and External reviewer
- Increase transparency from ASEAN Harmonization through common regulations and guidelines
- Language barriers: Some countries need to translate all templates & guidelines in their own languages.
- GRevP implementation should be done in the way to help all member states to reach equally efficient performance, then to be one element(other elements such as quality management system of RAs) for sharing/acceptance of review among countries

Notice for Good Review Practice (GRevP):Transparency & Interaction with Regulatory Authorities (3)

- GRevP is new topic that ASEAN harmonization never discusses. Capacity building is necessary:

Trainings especially Workshops with case studies and exercises, demonstrating how to fill the GRevP templates (example of filled templates) are required.

Mentor to help us develop GRevP templates and guidelines is more useful

Notice for Good Review Practice (GRevP):Transparency & Interaction with Regulatory Authorities (4)

- Some trainings related to GRevP are needed:

  GCP

  - for sponsors and CROs
  - for investigators
  - for Ethic committees
  - for GCP inspectors (needed to established)

Comparing the suitable GCP for drugs vs medical devices is also prefered

Notice for Good Review Practice (GRevP):Transparency & Interaction with Regulatory Authorities (5)

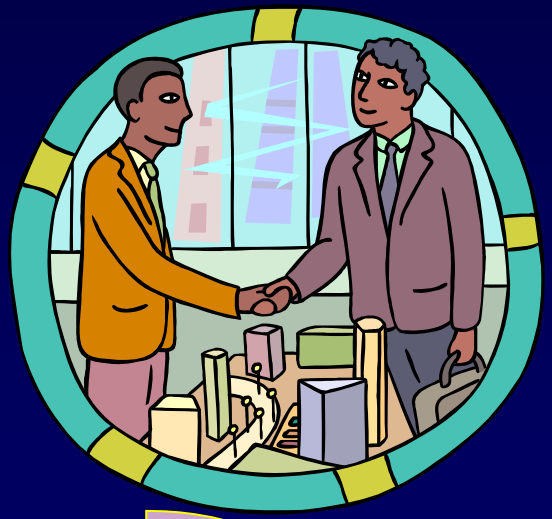
- Direct Networking among RAs for sharing information will be very useful and give a way to express transparency and trust/confidence among RAs wherever countries they are from: all regions, APEC/non APEC, developed/developing countries
- Training approach:

  - International cooperation e.g. ASEAN PPWG and MDPWG

  - National trainings

Key Success Factor

International ⟷ **National**



Partnership & Networks

Thank you very much for your attention