The ASEAN Picture of Harmonized Controls for Medical Devices

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2014 AHWP
AHC-AHWP JOINT WORKSHOP,
THE 18TH AHWP TC MEETING &
THE 19TH AHWP ANNUAL MEETING
NOV. 18-21, 2014
VISTA HALL, SHERATON GRANDE WALKERHILL, SEOUL, KOREA

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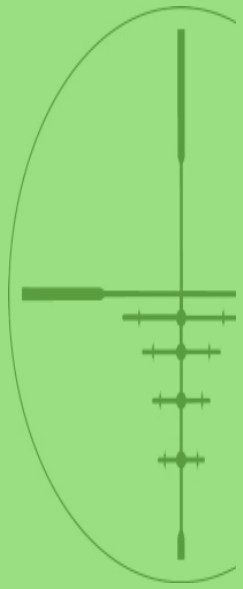
Background & History

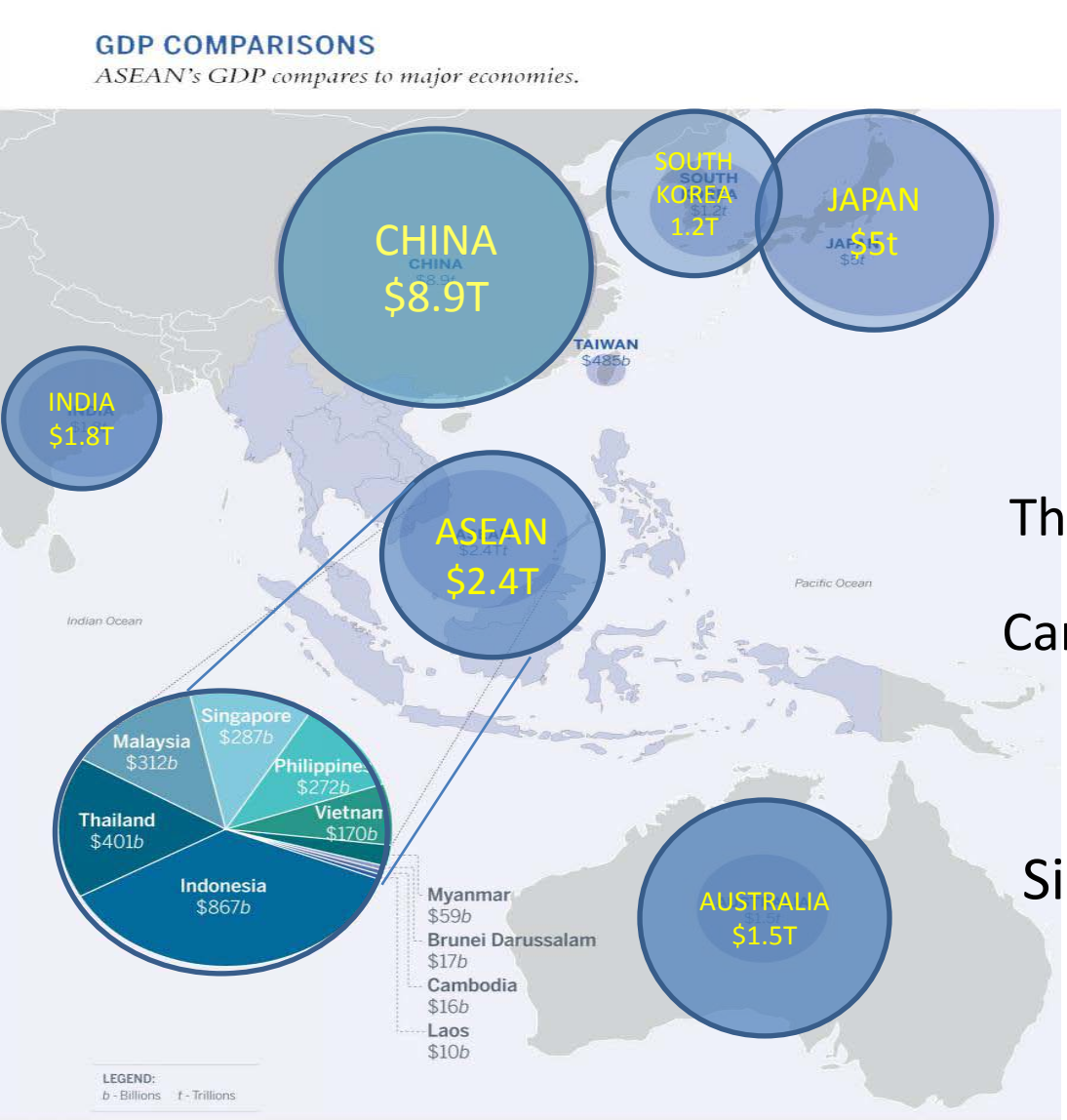
Scope

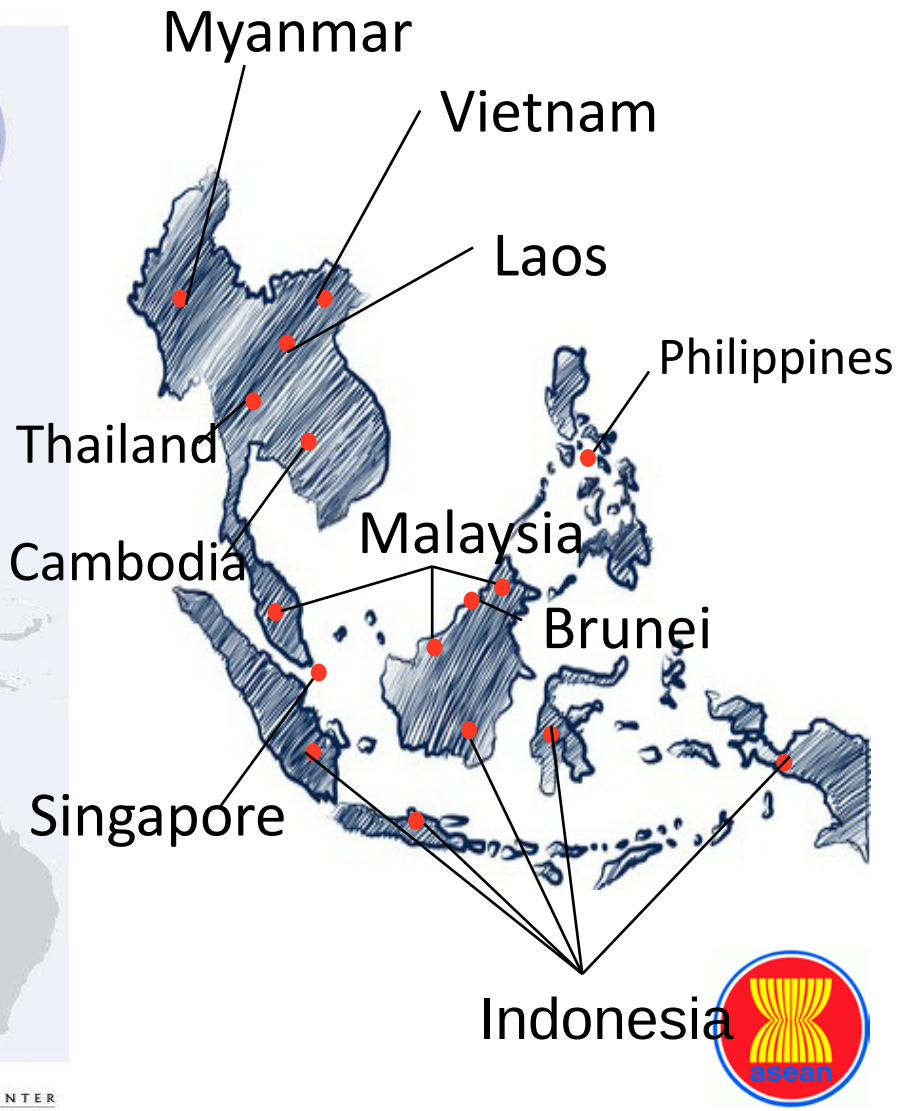


Impact

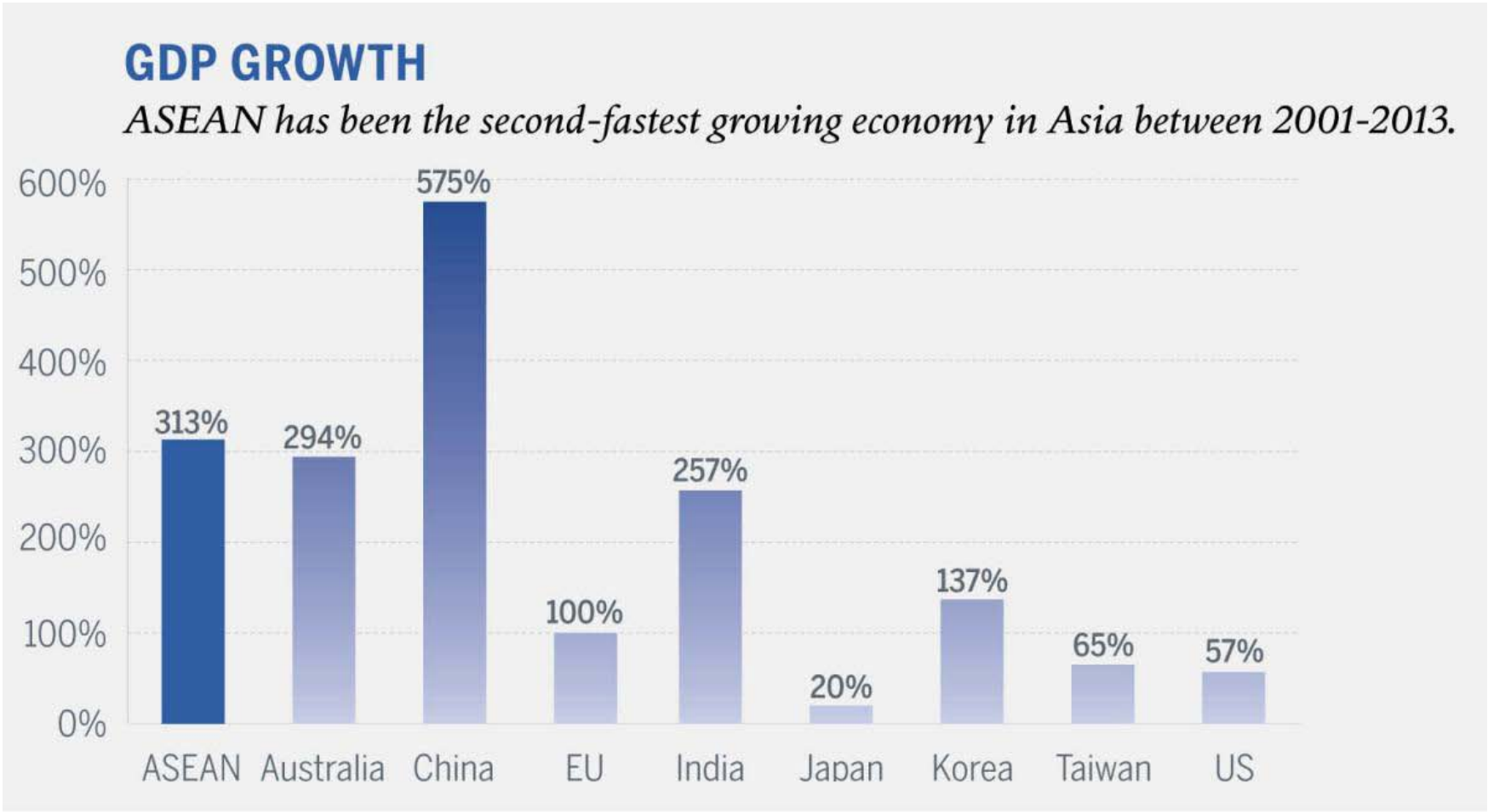
Moving Forward

ASEAN – Background

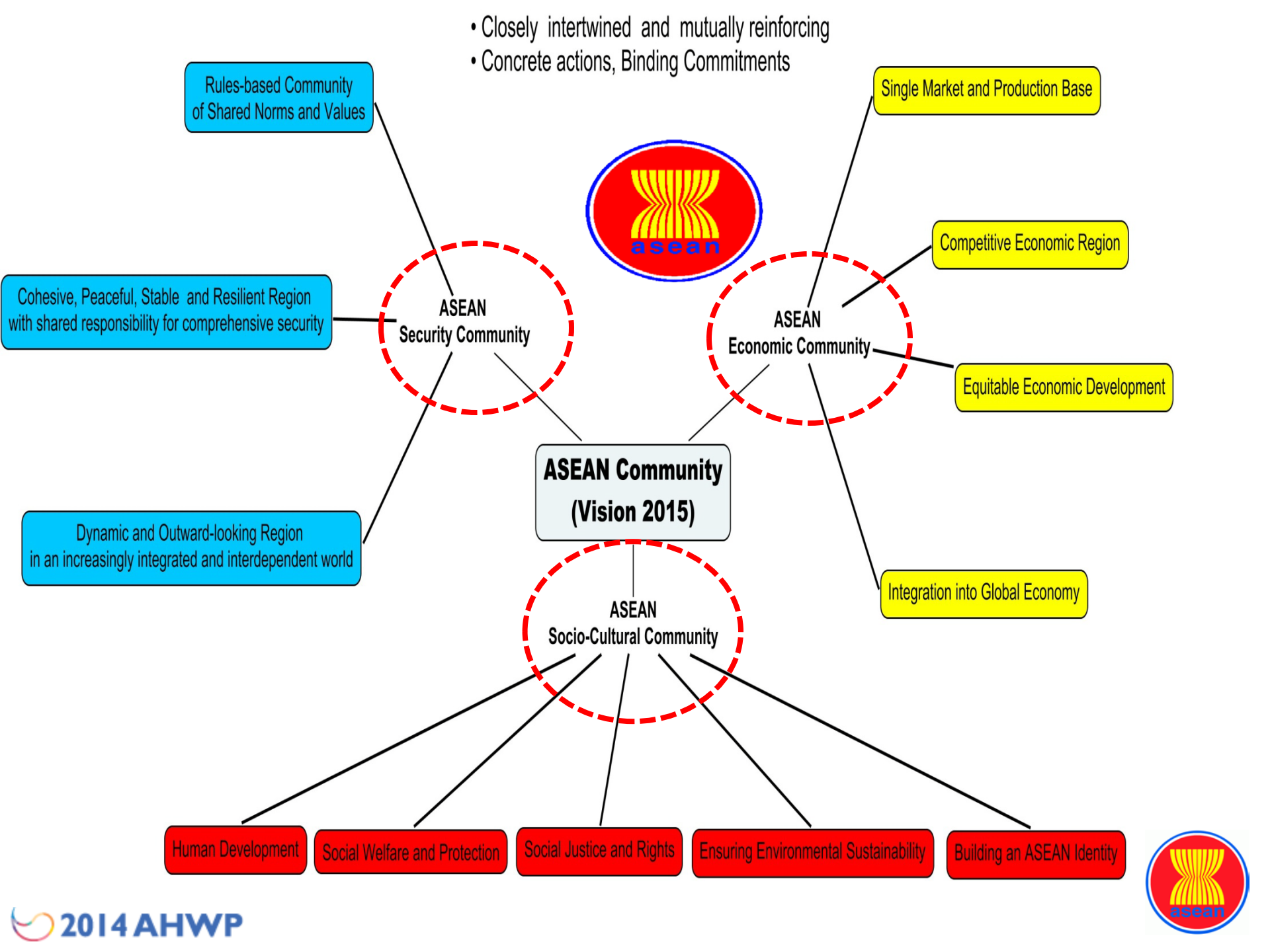




ASEAN – Background



Sources: ASEANstats, ASEAN Secretariat, 2013


• Closely intertwined and mutually reinforcing
• Concrete actions, Binding Commitments
Rules-based Community of Shared Norms and Values
Single Market and Production Base
Competitive Economic Region
Cohesive, Peaceful, Stable and Resilient Region with shared responsibility for comprehensive security
ASEAN Security Community
ASEAN Economic Community
Equitable Economic Development
ASEAN Community (Vision 2015)
Dynamic and Outward-looking Region in an increasingly integrated and interdependent world
Integration into Global Economy
ASEAN Socio-Cultural Community
Human Development
Social Welfare and Protection
Social Justice and Rights
Ensuring Environmental Sustainability
Building an ASEAN Identity
2014 AHWP

AEC – Background

- In the 12th ASEAN Summit in January 2007, the Leaders of all ASEAN Countries affirmed their strong commitment to accelerate the establishment of an ASEAN Community by **2015**

- The Leaders agreed to hasten the establishment of the ASEAN Economic Community by 2015 and to transform ASEAN into a region with free movement of goods, services, investment, skilled labor, and freer flow of capital.

ASEAN Progress

AEC Scorecard → **How is ASEAN progressing?**

- **Single market and production base**
- **Competitive Economic Region**
- **Equitable Economic Development**
- **Integration into the Global Economy**

Updated:
=79.7%
as of the 23rd ASEAN summit in October 2013

ASEAN Structure

Political-Security Community

Economic Community

Socio-Culture Community

ASEAN Economic Minister Meeting (AEM)

ASEAN Senior Economic Official Meeting (SEOM)

ASEAN Consultative Committee on Standards and Quality (ACCSQ)

- **WG 1** Working Group on Standards and Mutual Recognition Arrangements (MRAS)
- **WG 2** Working Group on Conformity Assessment
- **WG 3** Working Group on Legal Metrology
- **JSC EEE** Joint Sectoral Committee on Electrical and Electronic Equipment
- **RBPWG** Rubber-Based Product Working Group
- **ACC** ASEAN Cosmetic Committee
- **PPWG** Pharmaceutical Product Working Group
- **PFPWG** Prepared Foodstuff Product Working Group
- **MDPWG** Medical Devices Product Working Group → AMDD
- **TMHSPWG** Traditional Medicines and Health Supplements Product Working Group
- **APWG** Automotive Product Working Group

Genesis of AMDD

2007

12th ASEAN Summit-Establish AEC by 2015

AEC will establish ASEAN as a single market and production base.

ASEAN single market & production base - five core elements:

i. **free flow of goods;**
ii. free flow of services;
iii. free flow of investment;
iv. freer flow of capital; and
v. free flow of skilled labour

AEC Blueprint, Action Item :

-Harmonise standards, technical regulations and conformity assessment procedures through their alignment with international practices, where applicable

Harmonization of medical device regulation:-

- Reduce the time to market access & facilitate trade
- Reduce the cost to market
- Improve regulatory efficiency
- Enhancement of public health protection

Milestones of AMDD

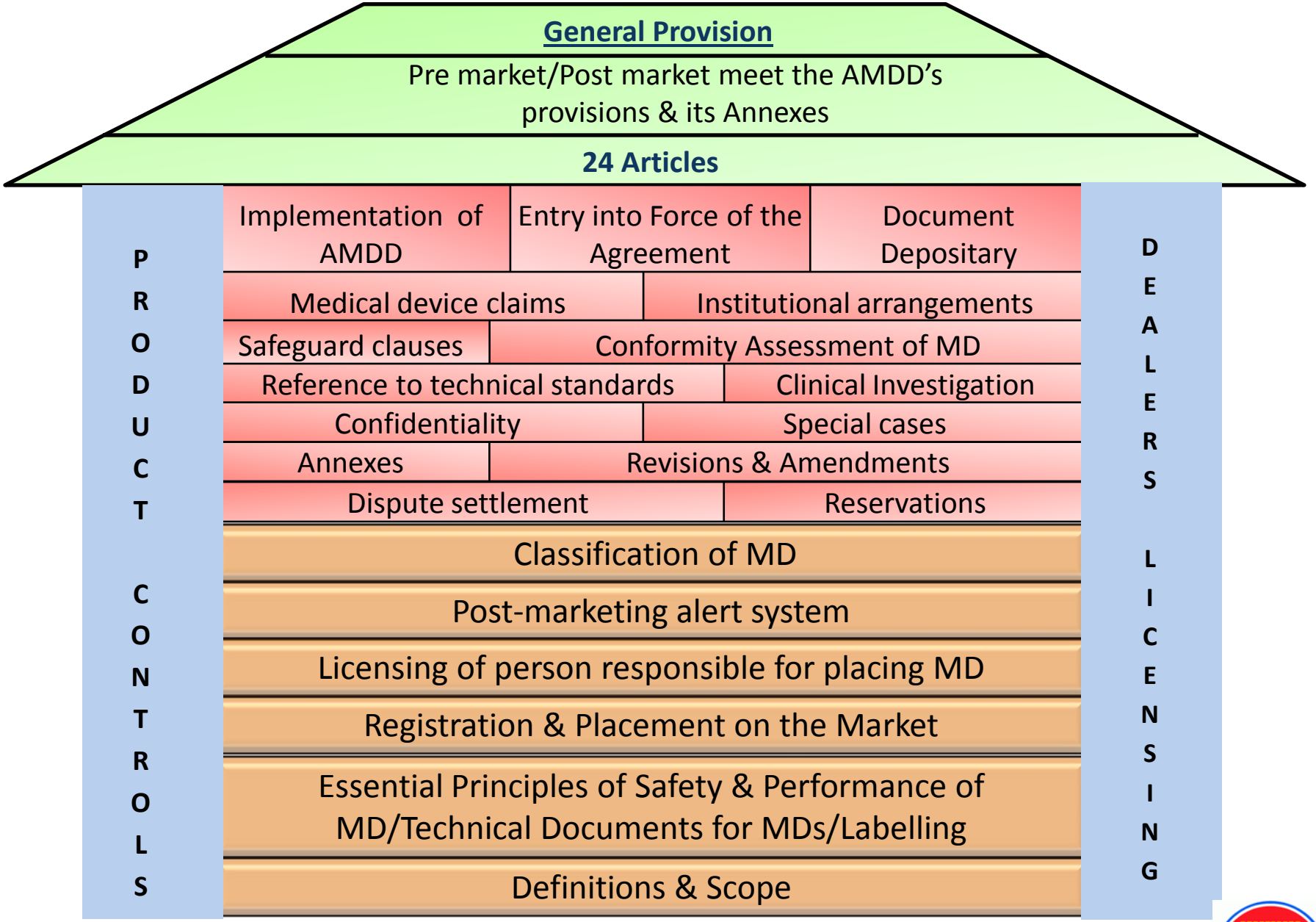
01.2007
- AMDD began in relation to the establishment of AEC

05.2012
- Development of AMDD:
  - National Consultation
  - National Consultation Feedback
  - Review
  - Incorporation of Amendments
  - Legal scrubbing by Member State
  - Legal scrubbing by ASEAN Secretariat's Legal Department
  - **Finalisation of AMDD (Version 15)**

10.2013
- Endorsement by ACCSQ
- Endorsement by SEOM

08.2014
- Signing of AMDD at AEM

01.2015
- AMDD becomes **effective** when ASEAN Member States (AMS) deposit instruments of ratification with ASEAN Secretariat General


General Provision
Pre market/Post market meet the AMDD's provisions & its Annexes
24 Articles
PRODUCT CONTROLS
Implementation of AMDD
Entry into Force of the Agreement
Document Depositary
Medical device claims
Institutional arrangements
Safeguard clauses
Conformity Assessment of MD
Reference to technical standards
Clinical Investigation
Confidentiality
Special cases
Annexes
Revisions & Amendments
Dispute settlement
Reservations
Classification of MD
Post-marketing alert system
Licensing of person responsible for placing MD
Registration & Placement on the Market
Essential Principles of Safety & Performance of MD/Technical Documents for MDs/Labelling
Definitions & Scope
DEALERS LICENSING

Impact Analysis to ASEAN Industry

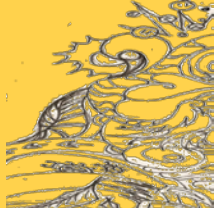
Benefits:

- Common MD Definition & Related Definitions
- Common Risk Classification
- Harmonised Technical Requirements for MDs
- Common Submission Dossier
- Common Post-Marketing Reporting Forms
- Opportunities for Regulatory Integration

Challenges:

- Teething Phase
- Industry's own Expectations

How does AMDD safe guard ASEAN healthcare objectives?



- Harmonisation of MD regulatory controls within ASEAN is critical
  - **Common requirements** for addressing the product life cycle which reduces the burden, complexity, and unpredictability for gaining market clearance.
  - **Reduce the complexity** needed to meet local requirements and improves the utilization of already stretched and limited human and financial resources.
  - **Facilitating cooperation** among regulators and the industry in conducting regulatory activities.
  - Common and transparent premarket evaluation, post market surveillance, uniform quality system with similar audit criteria, and common clinical safety performance.

- Harmonization of medical device regulation**:-**
  - **Reduce the time to market access & facilitate trade**
  - **Reduce the cost to market**
  - **Improve regulatory efficiency**
  - **Enhancement of public health protection**

- AEC will establish ASEAN as a single market & production base.

Highlights of 5 Articles

- Article 1. General Provision
- Article 2. Definitions & Scope
- Article 3. Essential Principles (EP) of Safety & Performance of MDs
- Article 8. Technical Documents for MDs
- Article 12. Post Marketing Alert System

Article 1. General Provision

➢ **Measures to be taken:**

- PRODUCTS (MDs)
  - meet the AMDD's provisions & its Annexes
- PERSON/REGISTRANT
  - Natural/legal person/authorized representative
  - Register with the Regulatory Authority (RA)
  - Apply for product pre-market approval

Article 2. Definitions & Scope

➢ Most important:

- **Definition of a MD**:
  - Align with GHTF
  - IVD definition , not separated as yet (next phase)

Other definitions: Adverse Events, FSCAs, Authorised Reps etc.

➢ Scope of AMDD:

- AMDD does not cover:
  - Human blood, plasma or blood cells of human origin or to devices that incorporate these
  - TTC – (Transplants or tissues or cells) or MDs incorporated with Human origin or Animal Origin

- *Unless in In-Vitro Diagnostic Devices (IVDDs) or TTC rendered non-viable during the manufacture of the MD.*

Article 3. Essential Principles (EP) of Safety & Performance of MDs

- **Medical Device:**

o Meet the Essential Principles (Reference: ANNEX 1)

o Product Owner (Equivalent to :-Legal Manufacturer)

- Prepares document to demonstrate conformity to:
  - General requirements:

    - Major safety and performance standards & requirements that apply to all MDs
  - Information to be provided with the medical device:

    - Instructions for use, labels
  - Clinical evidence

Article 8. Technical Documents for MDs

- Appropriate measures to *adopt and implement.*

- *Reference:*
  - Annex 4:

    ASEAN Common Submission Dossier Template (CSDT);
  - Annex 5:

    Post Marketing Alerts System (PMAS) Requirements; and
  - Annex 6:

    Components Elements of a Product Owner's or Physical Manufacturer's Declaration of Conformity (DOC)

Article 12.
Post Marketing Alert System

- Post market information in areas of:
  - device malfunction/deterioration/labelling inadequacies etc. (Field Safety Corrective Action - FSCA);
  - device-related adverse events (AE)
  - Must be:
    - reported to AMS
    - recorded and assessed by AMS
    - AMS ensure appropriate action is taken

- The AMS may inform the other AMS of the incidents (without prejudice to confidentiality restrictions)

Article 12.
Post Marketing Alert System

- Person responsible for placing the device in the market:-
  - Maintain all **records** for traceability of the medical device;
  - Inform the RA within the stipulated time
    - Upon company becoming aware of any AE *and*
    - When company performs or intends to perform a FSCA on a medical device

이미지 투데이 디자인소스

Thank you

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