Preparatory steps to Medical Device Controls: ASEAN experience centring on AMDD elements

International Medical Device Conference 2017, Penang

8-10th August 2017

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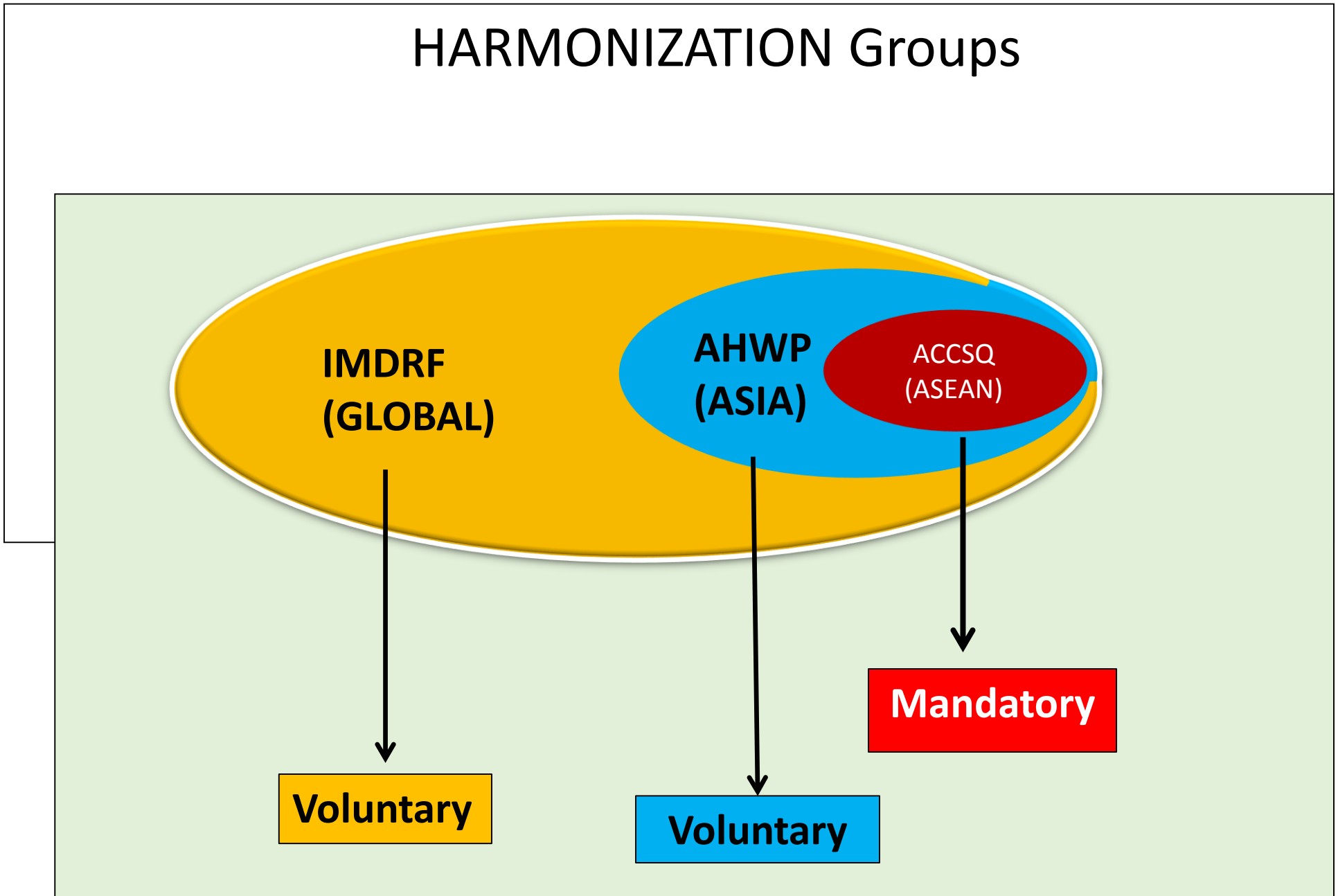
Indicators	Unit	2012	2013[p/]
Total land area	km2	***4,435,617***	**4,435,617**
Total population	thousand	***617,165***	**625,096**
Gross domestic product at current prices	US$ million	***2,320,840***	**2,398,154**
GDP growth	percent	***5.8***	**5.1**
International merchandise trade	US$ million	**2,476,427**	***2,510,127***
Export	US$ million	**1,254,581**	***1,270,467***
Import	US$ million	**1,221,847**	***1,239,660***
Foreign direct investments inflow	US$ million	***114,082***	**119,756**
Visitor arrivals	thousand	**89,225**	**-**

Sources ASEANstats,
ASEAN Secretariat

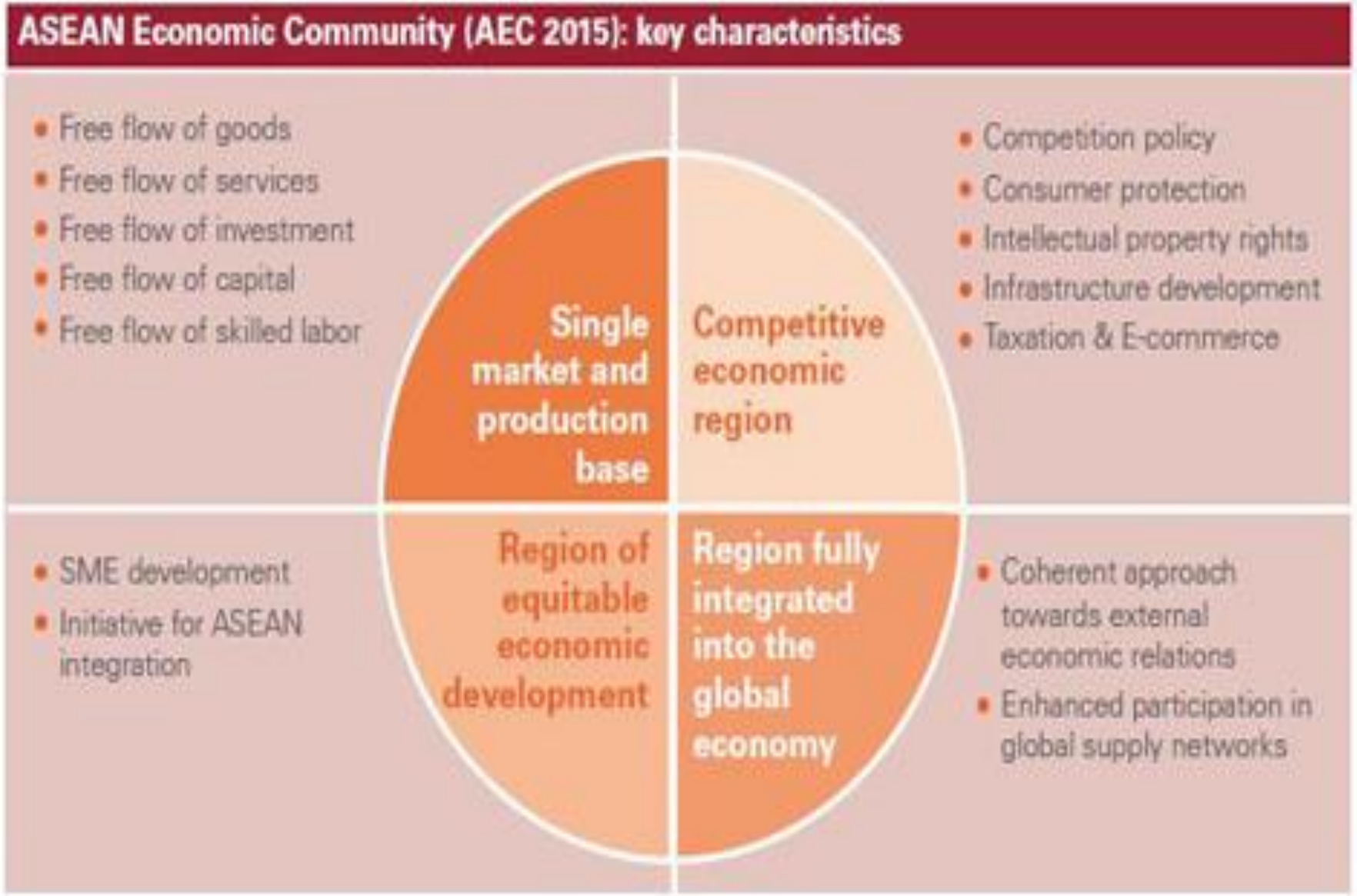
Cross culture...

- **Language: Tagalog, Bahasa Indonesia, Bahasa Malaysia, Thai, Vietnamese, Lao, Mynmar, Cambodia, English (commonly used language)**
- **Diverse culture**;
- **Timing: 2020 convergence of regulations**
- **Interests: Local, British, French, American, Dutch, Portugese**
- **Local Government**

HARMONIZATION OF MEDICAL DEVICES REGULATION



Principles of ASEAN ECONOMIC COMMUNITY



Medical device Regulation toward the AEC 2015

Goal of creating an ASEAN Economic Community by 2015, with fast-track integration of the 12 priority sectors

1. Agro-base product	**5. Electrical**	**9. Health care product (drug, traditional drug, cosmetic and Medical Devices)**
2. Air Travel	**6. Rubber base product**	**10. Textiles and apparels**
3. Automotive	**7. Tourism**	**11. Wood-based product**
4. e-ASEAN	**8. Fisheries**	**12. Logistics Services**

ASEAN Structure

Political-Security Community

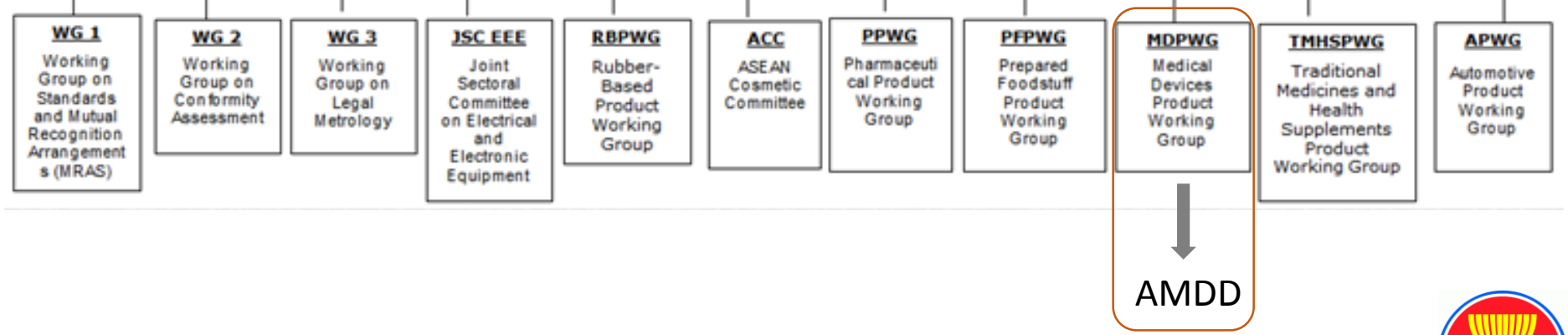
Economic Community

Socio-Culture Community

ASEAN Economic Minister Meeting (AEM)

ASEAN Senior Economic Official Meeting (SEOM)

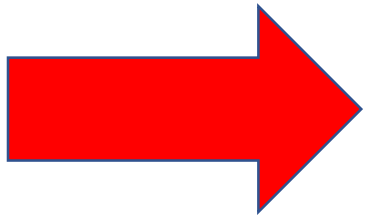
ASEAN Consultative Committee on Standards and Quality (ACCSQ)



AMDD

Why convergence is critical in ASEAN

- Common requirements for addressing product life cycle
- Reduce complexity needed to meet local requirements
- Facilitating cooperation among regulators
- Common and transparent premarket evaluation, post market surveillance and uniform quality system



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

ASEAN Economic Community Blueprint– Medical Device PWG AGENDA

HARMONISED REGULATORY FRAMEWORK: THE ASEAN MEDICAL DEVICE DIRECTIVE

HARMONISED PREMARKET SUBMISSION FORMAT: ADOPTION OF THE COMMON SUBMISSION DOSSIER TEMPLATE

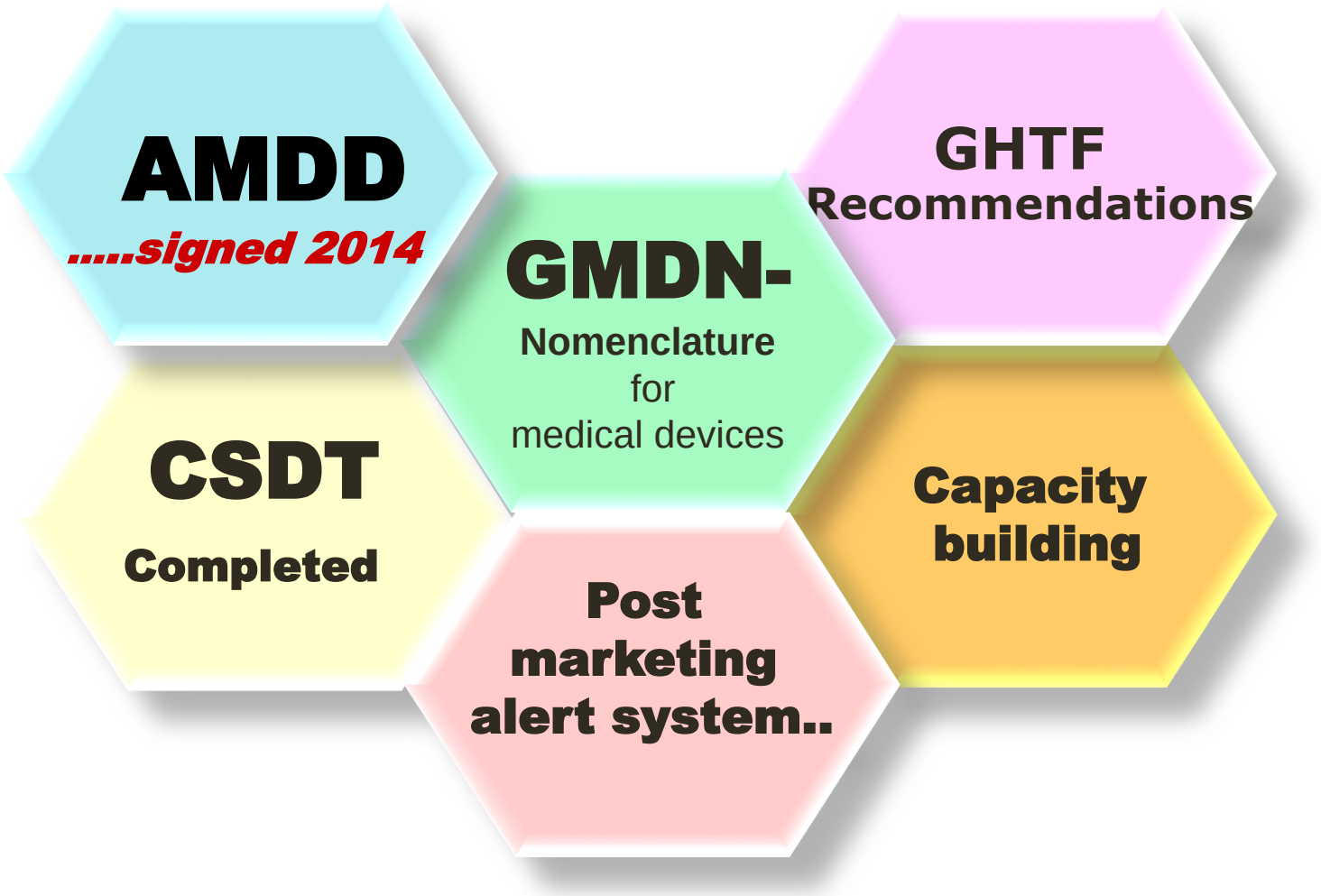
HARMONISATION

HARMONISED SET OF VOLUNTARY STANDARDS IN ASEAN:BASED ON IEC AND ISO STANDARDS

SHARING OF : POST MARKET SAFETY INFORMATION AMONG ASEAN MEMBER STATES

MDPWG WORK PROGRAMME

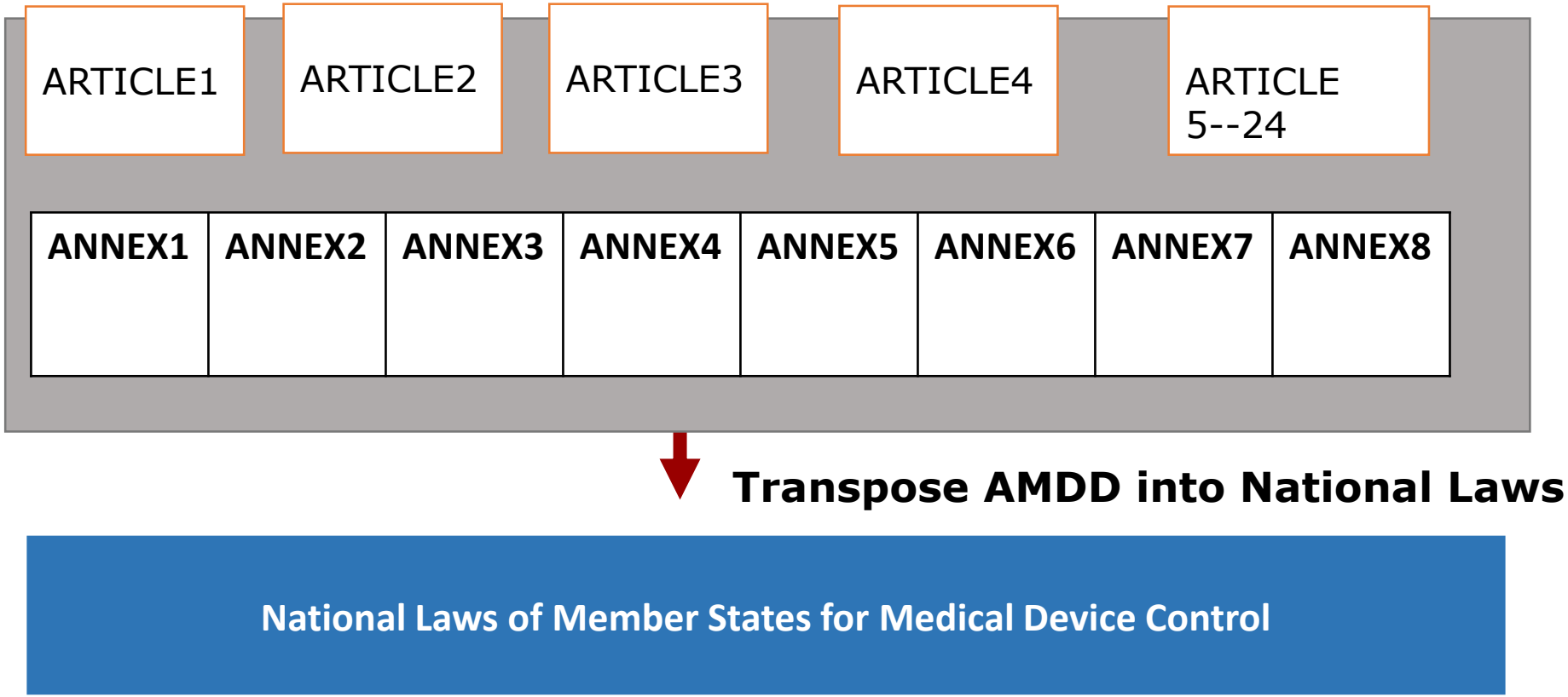
*To facilitate the **integration** of the medical devices sector through elimination of technical barriers to trade in ASEAN*



Major Requirements of the ASEAN Medical Device Directive

- Licensing of Establishment
- Medical Device Registration
- Device Classification
- Definition Of Medical Device
- Common Submission Dossier Template
- Post-market requirements
- Establishment of ASEAN Medical Device Committee (AMDC)
- Clinical Trials

AMDD STRUCTURE Uniform Regulatory Structure



Article No.	Title
1	General Provisions
2	Definitions & Scope
3	Essential Principles of Safety & Performance of MD
4	Classification of MD
5	Conformity Assessment of MD
6	Registration & Placement on the Market
7	Licensing of person responsible for placing MD on the markets of Member States
8	Technical Documents for MDs
9	Reference to technical standards
10	Labelling
11	Medical device claims
12	Post-marketing alert system
13	Clinical Investigation
14	Institutional arrangements
15	Safeguard clauses
16	Confidentiality
17	Special cases
18	Implementation
19	Revisions, Modifications and Amendments
20	Dispute settlement
21	Reservations
22	Entry into Force
23	Annexes
24	Depositary

24 Articles

- Intend to reduce the time-to-market & cost of medical devices
- Patient safety standards will improve across the region.

24 Articles

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A Uniform Regulatory Framework for member economies

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24 Articles

A Harmonised Requirements for Medical Devices

8 Annexes

Annex No.	Title
1	Essential Principles for Safety & Performance of MDs
2	Risk Classification Rules for MDs other than In Vitro Diagnostic (IVD) MDs
3	Risk Classification Rules for IVD MDs
4	ASEAN Common Submission Dossier Template
5	Post-Marketing Alert System (PMAS) Requirements
6	Components Elements of a Product Owner's or Physical Manufacturer's Declaration of Conformity (DOC)
7	Labelling Requirements
8	Clinical Investigation

Milestone of AMDD

July 2007

- AMDD begun in relation to the establishment of AEC

May 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)**

Sept 2013

- Endorsement by ACCSQ
- Endorsement by SEOM

Dec 2014

- Signing of AMDD at AEM

Jan 2015-

Dec. 2020

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

ONCE the AMDD is signed..

- AMDD **does not enter into force** until **instruments of ratification** are deposited with ASEAN Secretary-General.
  - No deadline for deposition but member states have agreed in principle to begin transposing regulatory controls to national legislation.
- Administrative elements of AMDD would begin to be managed by **ASEAN Medical Device Committee (AMDC)**,
- **Amendments** to technical requirements to ensure AMDD is continuously **aligned** to **international best practices**
- Further areas of harmonization eg IMDRF

PROGRESS OF MDPWG TO AMDC

- Establishment of the ASEAN Medical Device Committee (AMDC)
- To coordinate,review and monitor the implementation of AMDD
- Comprise of representatives from Regulatory Authority of each Member State
- The ACCSQ and ASEAN Secretariat shall support in coordinating and monitoring the implementation of AMDD
- AMDC may establish ASEAN Medical Device Technical Committee (AMDTC) to assist the AMDC in reviewing the technical safety and safety issues.
- Milestone for completion of transposition process and submission of instrument of ratification by 2020. The milestone will include, among others, the following items

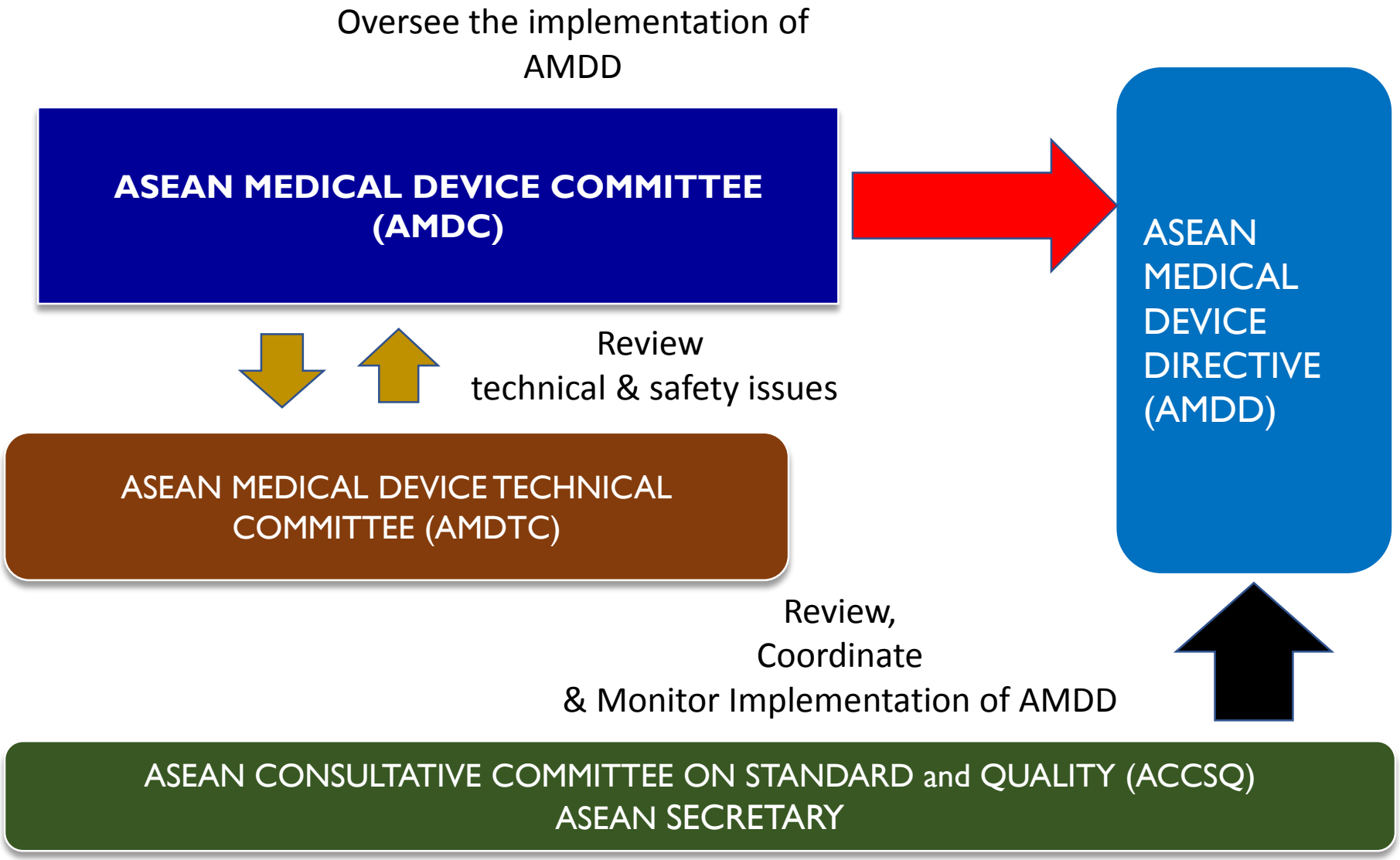
(i) Development of Guidelines for implementation of AMDD,

(ii) Implementation of AMDD in phases,

(iii) Monitoring of the implementation of AMDD

(iv) Development of a matrix on common interpretation of AMDD

AMDD INSTITUTIONAL STRUCTURE



Updates on the AMDC Sept 2017

- AMDTC to monitor the progress as follows
  - Risk Classification-
    - To have a list of comprehensive risk classification
    - To compile and identify similarities and difference among member countries
  - Borderline Products
    - To discuss the devices and the borderline products and submit the complete list for endorsement
  - Grouping
    - Agreed for member states to share and present the regulation on grouping systems
  - Workplan for AMDTC

AMDD ARTICLE	PROVISION	MALAYSIA	SINGAPORE	CAMBODIA	INDONESIA	LAOS	PHILIPPINES	THAILAND	MYNMAR
	STRUCTURE	Y	Y	Y	Y	Y	Y	Y	Y
	ACT	Y	Y	Y	Y	Y	N/A	Y	Ongoing
4	CLASSIFICATION OF MEDICAL DEVICES	Y	Y	Y	Y	Y	N/A	Y	Y
6	REGISTRATION	Y	Y	Y	Y	Y	Y	Y	N/A
7	LICENSING	Y	Y	Y	Y	Y	Y	Y	Y
10	LABELLING	Y	Y	Y	N/A	Y	N/A	Ongoing	N/A
12	POST-MARKETING ALERT SYSTEM	Y	Y	N/A	Y	Y	Y	Y	Y
	RATIFICATION	2018	Done	2018	2019	Done	2018	End of 2017	2018

AMDD CURRENT TRANSPOSITION STATUS IN MEMBER COUNTRIES

Transposition of AMDD	Member Economies	Comments
Full Implementation	3	Singapore, Laos PDR Vietnam
Ongoing Ratification	7	Brunei, Cambodia, Indonesia Malaysia Myanmar Philippines Thailand

NEW PROGRAM

- Interpretative Notes of AMDD
- Development of GANTT Chart for Phase Implementation of AMDD
- Development of Guidelines on Post Market Surveillance

The reality of AMDD

- It defines submission of technical requirements to be harmonized
- It requires Member countries to register products and license establishments
- It states that development of the guidelines and standards that follows internationally recognized institutions and organisations

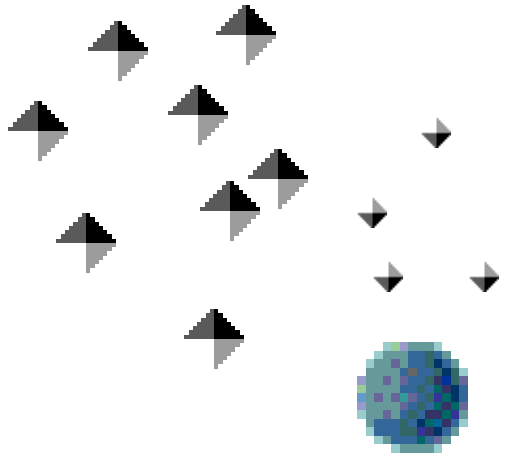
- Flexible in that Member states however, still retain their sovereign rights on how registration and licensing decisions
- It allows member countries to implement country specific measures of controls
- Focusing only on certain important aspect of medical device regulatory control and not aimed in harmonizing all of it

Impact Analysis on ASEAN Industry

- Harmonised Technical Requirements (CSDT)
- Common Definition
- Common Risk Classification
- Use of International Standards
- Post market vigilance and surveillance systems
- Opportunities for regulatory integration
- Teething Phase
- Industry’s own Expectations

Challenges

- Language of AMDD
- The state of readiness of Member States to transpose the AMDD?
- Factors that can influence the speed of transposition
- Capacity Building
- PMS alert system



Thank You