



# UPDATES IN ASEAN

**26<sup>th</sup> Global Harmonization Working Party Meeting**

16 February 2023

**ONE VISION, ONE IDENTITY, ONE COMMUNITY**



# ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS & QUALITY (ACCSQ)



**A**SEAN, through the ASEAN Consultative Committee for Standards and Quality (ACCSQ):

- established in 1992 with the aim to eliminate technical barriers to trade (TBT) related to Standards, Technical Regulations and Conformity Assessment Procedures (STRACAP).
- addressing technical barriers to trade (TBT) to ease movements of goods across the region, and with the other trade partners.
- non-tariff barriers including technical barriers to trade posed by standards, technical regulations, and conformity assessment procedures can limit the flow of goods and the growth of businesses.

## BENEFITS OF TBT ELIMINATION



### Government

- Increase GDP
- Better international trade relations



### Business

- Lower trade costs
- Increased business opportunities



### Citizens

- Increased variety of consumer choices
- Competitive price, quality

# ASEAN CONSULTATIVE COMMITTEE FOR STANDARDS & QUALITY (ACCSQ)

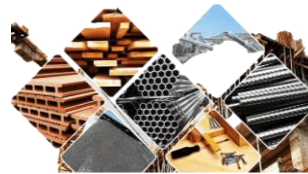
## PRIORITY SECTORS



**Agro-based products**  
(e.g Prepared foodstuff)



**Automotive products**



**Building & Construction**



**Rubber based products**



**Electrical & Electronics Equipment**



**Healthcare products**  
(Cosmetics, Medical Device, Pharmaceutical, Traditional Medicines and Health Supplements)

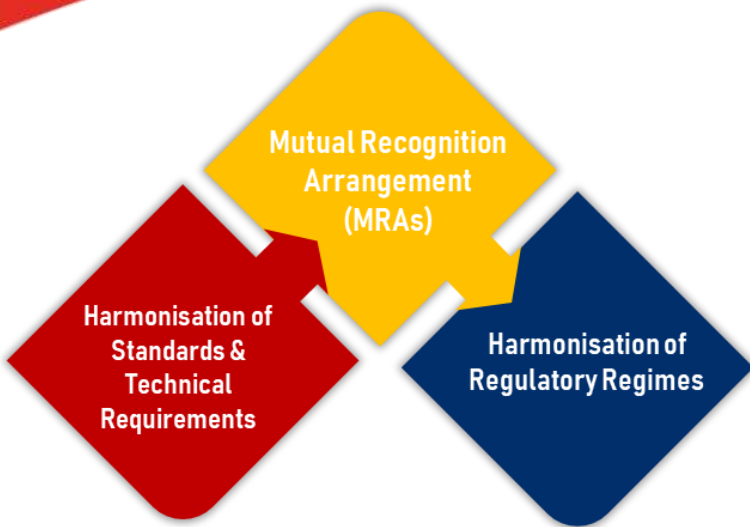


**Wood-based products**



**Digital Trade**

# ADDRESSING TECHNICAL BARRIERS TO TRADE



- ASEAN seeks to establish coherent regulatory regimes in ASEAN.
- Reference Documents:
  - ASEAN Principles on Harmonisation of Regulatory Regimes

## Harmonisation of Regulatory Regimes

1. Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme, and ASEAN Cosmetic Directive (2 September 2003)
2. Agreement on the ASEAN Harmonised Electrical and Electronic Equipment Regulatory Regime (9 December 2005)
3. ASEAN Medical Device Directive (21 November 2014)
4. ASEAN Food Safety Regulatory Framework Agreement (for signing)
5. ASEAN Agreements on Regulatory Framework for Traditional Medicines (for signing)
6. ASEAN Agreements on Regulatory Framework for Health Supplements (for signing)

# ASEAN Medical Device Committee (AMDC)

## Action Plans 2016 - 2025

### Activity Programme

- Strengthening the framework for cooperation in standards development to ensure relevant harmonised standards are available to support market integration, building upon the ASEAN Guidelines for Harmonisation of Standards.

### AMDC Activities

- Harmonised Risk Classification for Medical Devices and make harmonised decision on Borderline Products
- Adoption of harmonised Medical Devices Standards which was earlier identified by AMDC.

### Progress

- As of the 11th AMDC Meeting, 295 Risk Classification and 194 Borderline Products have been harmonized.

# ASEAN Medical Device Committee (AMDC)

## Action Plans 2016 - 2025

### Activity Programme

- Review and accelerate ongoing market integration initiatives which covers existing ACCSQ Mutual Recognition Arrangements (MRAs) and harmonised regulatory regimes with a view to enhancing effectiveness in removing technical barriers to trade.

### AMDC Activities

- Implementation of ASEAN Medical Device Directive (AMDD).

### Progress

- Ongoing transposition of AMDD to the national regulation.
- Development of guiding principles such as Common Submission Dossier Template (CSDT), Post-Market Surveillance (PMS), Registration and Licensing Guidance, and Interpretative Notes of Implementation of AMDD has been completed.
- Ongoing implementation of AMDD in phases.

# ASEAN Medical Device Committee (AMDC)

## Action Plans 2016 - 2025

### Activity Programme

- Coordinate and cooperate with regard to representation on new and developing issues in international and in Asia Pacific regional organisations.

### AMDC Activities

- Co-operation/ collaboration with international/regional organisations related to medical device i.e. GHWP and IMDRF.

### Progress

- Ongoing participation in GHWP and working in parallel with IMDRF on technical harmonisation efforts.
- Current ASEAN representation in GHWP TC.



# THANK YOU!



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