ASEAN Regulatory Harmonisation and Approval Process

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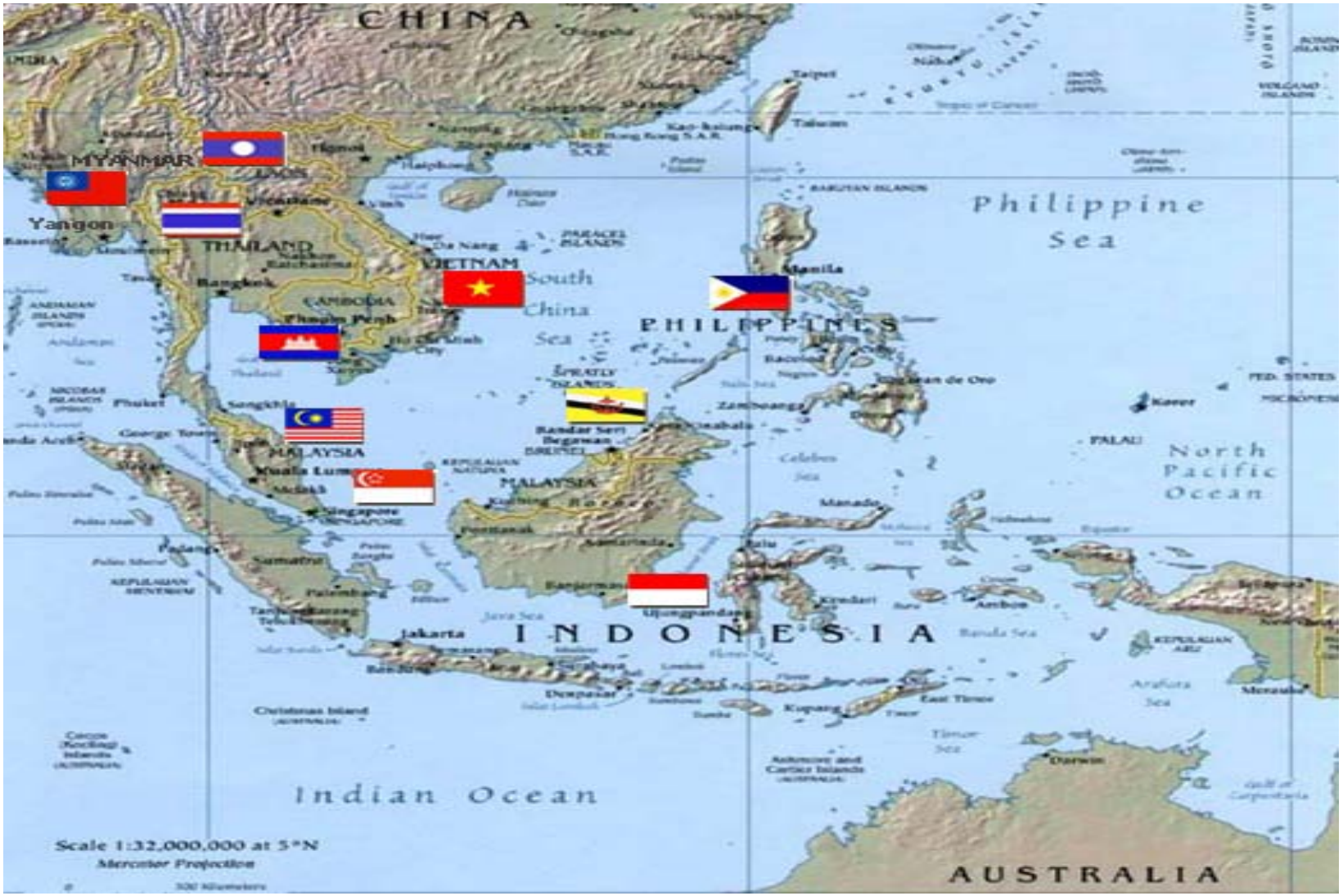
Presentation Outline

- About ASEAN
- Harmonisation Initiatives through Pharmaceutical Product Working Group
- An Informal Joint Evaluation
- Issues for New Products
- Impact of Harmonisation
- Key Issues in Harmonisation
- Conclusion

ASEAN –Association of South East Asian Nations



Facts

- ASEAN region has a population of about 583 million
- Total area of 4.5 million square kilometers
- Combined gross domestic product almost US$ 1,100 billion
- Total trade of about US$ 1,600 billion

History

- Association of Southeast Asian Nations (ASEAN) established on 8th Aug 1967 in Bangkok by 5 original members namely Indonesia, Malaysia, Philippines, Singapore and Thailand
- Brunei Darussalam joined on 8th Jan 1984
- Vietnam on 28th July 1995
- Lao PDR and Myanmar on 23th July 1997
- Cambodia on 30th April 1999

Ultimate Goal of the ASEAN

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**

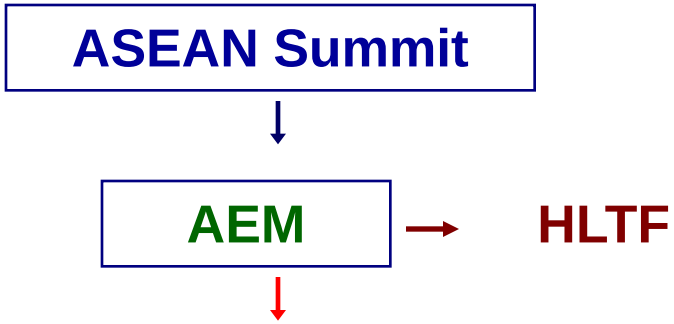
ASEAN FREE TRADE AREA

- ASEAN FREE TRADA AREA (AFTA) is a collective effort by ASEAN to reduce/eliminate tariffs in intra-ASEAN trade in the goods sector.
- Objective of AFTA is primarily to enhance ASEAN's position as a competitive production base for regional and global markets
- The ASEAN population provides enormous potential for market expansion.
- Trend of increasing intra-ASEAN trade

Technical Barrier to Trade

- The **ASEAN Consultative Committee for Standards and Quality (ACCSQ)** was formed in 1992 to facilitate and complement the ASEAN Free Trade Area (AFTA).
- In 1997, the ASEAN regulatory bodies were authorized to achieve mandate of eliminating technical barrier to trade.
- Efforts to harmonize regulatory requirements amongst ASEAN was initiated through the ASEAN Consultative Committee for Standards and Quality (ACCSQ) in 1998.
- Concept of ASEAN pharmaceutical harmonization was presented by Malaysia and agreed upon by the Senior Economic Officials Meeting (SEOM) in 1999.
- The **Pharmaceutical Product Working Group (PPWG)** was formed in 1999. Malaysia hosted the 1st PPWG meeting and was appointed the Chair and Thailand the Co-Chair.

Economic Cooperation



SEOM

ACCSQ

WGs

WG 1 on MRAs & Standards –
WG 2 on on Accreditation and Conformity Assessment –
WG 3 Legal Metrology –

PWGs

-ACC (ASEAN Committee on Cosmetic)
-**PPWG (Pharmaceuticals PWG)**
- EE PWG (Electrical and Electronic PWG)
- Pf PWG (Prepared Foodstuff PWG)
-TMHS PWG (Traditional Medicine & Health Supplement PWG)
- MD PWG (Medical Devices PWG)
- A PWG (Automotives PWG)
- RB PWG (Rubber-based PWG)
- WB PWG (Wood-based PWG)

Objective of Pharmaceutical Product Working Group (PPWG)

- To develop harmonization schemes of pharmaceutical regulations of the ASEAN member countries to complement and facilitate the objective of AFTA, particularly the elimination of technical barriers to trade posed by regulations, however without compromising product quality, efficacy and safety.

PPWG Activities

- Exchange of information on existing requirements and regulations
- Review requirements and regulations, and conduct comparative studies
- Study other harmonized procedures and regulatory system
- Establish common technical documents
- Develop technical requirements

Harmonisation Initiatives and Achievement

- Undertake study of regulatory system in place
- Twinning systems to enhance regulatory capacity and resource development
- Extensive training
- Devise ASEAN Common Technical Requirements (ACTR) and ASEAN Common Technical Dossier (ACTD)
- Harmonise labelling standards
- Formalise a post-marketing alert system for defective and unsafe pharmaceutical products

Harmonisation Initiatives

- Common Standard for GMP
- Common Approach for acceptance of BA/BE Study Report and Inspection
- Adopting a harmonised placement system for pharmaceutical products
  - Mutual acceptance of product evaluation
  - Joint evaluation for priority products
  - A central regulatory body

An Informal Joint Evaluation

- ASEAN Joint Review Meeting on Antimalarial Fixed Dose Combination (FDC) of Artesunate-Mefloquine (ASMQ)
- Artesunate-Mefloquine was developed through a collaborative programme, co-ordinated jointly by Drugs for Neglected Diseases initiative (DNDi) and WHO/ TDR
- It is one of the first line Antimalarial Combination Therapy treatments recommended by WHO for uncomplicated *falciparum* malaria in Asia and Latin America .

An Informal Joint Evaluation

- Common approach facilitates registration process
- Prelude to Common Product Placement System
- Issues for new products

Issues for new products

- Definition of new products
- Registration status in other countries
- WHO prequalification
- Disease control program
- Clinical trial

Impact of Harmonization

- Public Health
  - Improve Quality, Safety & Efficacy
- Patients & Consumers
  - Improve access & availability
- Industry
  - Harmonised standards facilitates trade
- Regulatory Authorities
  - Mutual understanding, efficient use of resources

Key Issues in Harmonisation

- Political commitment
- Regulatory infrastructure
  - Legal, physical, financial
- Human resource
  - Capacity & capability
  - Gaps
- Implementation
  - Understanding & interpretation
- Country specific requirements
  - Variations
- Industry involvement
  - Technical discussion groups

Conclusion

- Trade globalisation has prompted the need for strategic partnership. Harmonised standards are important in facilitating and liberalising trade and investment.

- Regional harmonisation can only be achieved by bridging the gaps between member countries in the establishment of regulatory systems and implementation of common requirements.

- Despite challenges, PPWG will move forward towards creating a single pharmaceutical market in the region.


Thank You