UPDATES ON ASEAN MEDICAL DEVICE REGULATIONS AND WAY FORWARD
(INDUSTRY PERSPECTIVE)

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A Promise for Life

ESTABLISHMENT

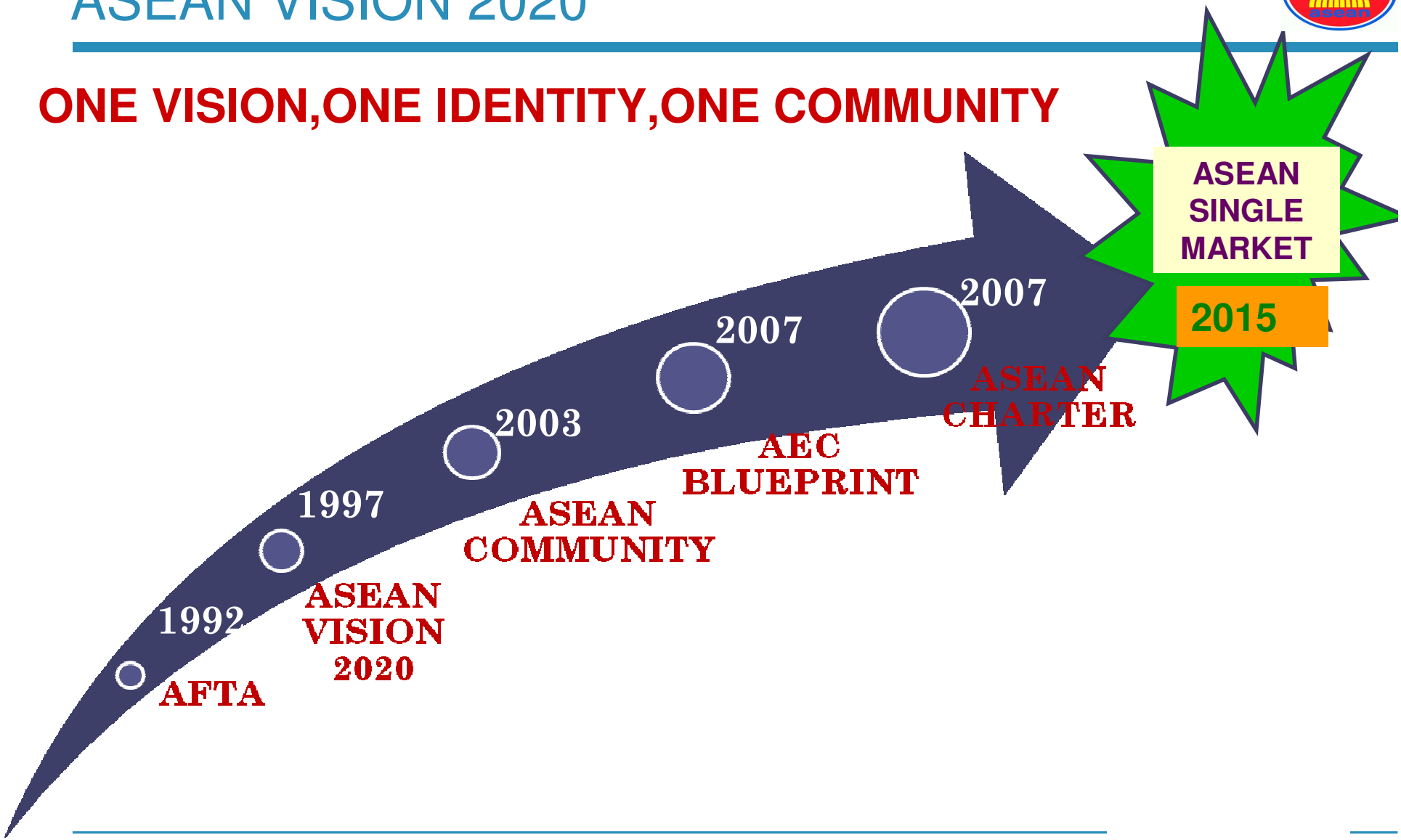
•The Association of Southeast Asian Nations, or ASEAN, was established on 8th August 1967 in Bangkok, Thailand, with the signing of the *ASEAN DECLARATION* (Bangkok Declaration)

•Brunei Darussalam then joined on 8 January 1984, Vietnam on 28 July 1995, Lao PDR and Myanmar on 23 July 1997, and Cambodia on 30 April 1999 Member States of ASEAN.

•Currently only 7 ASEAN countries i.e. Singapore, Malaysia, Indonesia, Thailand, Vietnam, Philippines, and Myanmar have laws or administrative guidelines that govern medical devices. Brunei, Cambodia, and Laos - are currently working on developing laws or guidelines.

ASEAN VISION 2020

ONE VISION,ONE IDENTITY,ONE COMMUNITY



GOALS AND OBJECTIVES

- ASEAN's Goals
  - Promoting mutual economic development and competitiveness in Southeast Asia
  - Eliminating trade and investment barriers within the region
  - Harmonizing industry regulations.

- The Medical Device Product Working Group (MDPWG) is the ASEAN committee responsible for medical device regulatory harmonization .

- MDPWG is crafting to harmonize Medical Device regulations in the form of ASEAN Medical Device Directive (AMDD).

KEY FEATURES - ASEAN MDD

- Registration of medical device prior to the placement in the market
- All 5 elements of GHTF Conformity Assessment Guidance (QMS, Post-Market Surveillance, Technical Documentation, Declaration of Conformity and registration of manufacturers and their devices) are incorporated
- Registration of Dealers of Devices
- Regulatory authority of individual ASEAN member state retains authority over licensing of dealers and devices
- Clinical investigations must be done to Helsinki Declaration, to prevent ASEAN from being a ground for unethical clinical investigations
- AMDD treats in vitro diagnostics (IVDs) as Medical Devices.

PROGRESS SO FAR

- Roadmaps formulated to implement the ASEAN Common Submission Dossier Template (ACSDT)

  – Pilot programme for the implementation of the ACSDT (2006-2007)
  – Guidance for the preparation of product registration application for general medical devices (provides general recommendations on the content of the formatted elements)
  – Full implementation of the ACSDT within AMDD

- Efforts are made to achieve the target of finalising and signing the ASEAN Medical Device Directive by 2013 -2014 by the ASEAN Member States to harmonise the medical device regulatory requirements.

- Capacity Building

9TH ASEAN ACCSQ MEETING - PENANG

- The 9th ASEAN Consultative Committee on Standards & Quality (ACCSQ) medical device product working group (MDPWG) ASEAN was held on1-3rd April 2009 in Penang, Malaysia.

- The Aim for the ASEAN Consultative committee was spelled out at the initiation of the meeting. - Aim to harmonize Standards, Conformity assessment procedures so as to promote trade. Priority was highlighted for
  - Economic integration
  - Trade facilitation measures.

- The MDPWG timelines for amending , developing and implementing the AMDD were defined as follows
  - December 2013 - Final draft to be signed
  - December 2014 - Transposing into national regulation

10th ASEAN ACCSQ MEETING - LAOS

- Meeting was held in Laos from 27th – 29th OCT 2009
- Key measures to be taken with regards to the Road Map for the integration of Medical Devices were discussed
  - Common Submission Dossier Template for product approval in ASEAN
  - Abridged approval process
  - Harmonised System of placement of medical devices into the ASEAN markets based on a common product approval process
  - Post-Marketing alert system for defective or unsafe medical devices or equipment
  - Participation in Asian Harmonization Working Party (AHWP) and Global Harmonisation Task Force (GHTF) on technical harmonisation efforts

10th ASEAN ACCSQ MEETING - LAOS

CAPACITY BUILDING

- Pre Market approval
  - GHTF classification with detailed list of product category in each class
  - Preparation of CSDT by choosing products from each class indigenously manufactured in ASEAN while comparing the requirements stated in STED, PMA,510K
  - Risk Assessment Rules in general to be applied for product approval
  - Adopt GHTF clinical trial (SG5) in principle include GCP, ISO 14155
- Post Market approval
  - Good Distribution Practice (GDP), Good Importing Practice (GIP)
  - Quality System Audit for Regulatory authorities
  - GHTF founding members experience to be taken into account for the guidelines to register and monitor Conformity Assessment Bodies
  - Process Validation and design Verification & Validation
  - Statistical sampling products from the market.

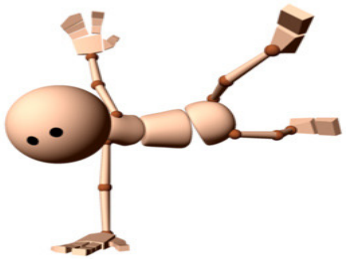
10th ASEAN ACCSQ MEETING - LAOS

CAPACITY BUILDING

- Legislations
  - Understand legal status and commitment impact of ASEAN Charter, AEC Blue print
  - Roadmaps for integration and Dispute Settlement Agreements

- Others
  - Establishment of Essential Testing Laboratories
  - Controlling system of refurbished medical devices
  - Reference Standard Sourcing and availability especially for IVD devices

ISSUES



- Nomenclature
  - Decision on adoption of Common Nomenclature System is pending
- Labeling
  - Some countries will accept English labeling to be the only requirement, while other countries want labels translated into native languages as well.
  - Industry proposes that Labeling should be standardized in English and labels should contain standardized symbols.
- Third Party Assessment
  - No final consensus on AMDD draft with regards to third party assessment bodies.

WAY FORWARD (INDUSTRY PERSPECTIVE)

OBSERVATION AND RECOMMENDATIONS

- Capacity Building
  - Training and capacity building should be held or coordinated at the ASEAN level
  - Include exchange programs between ASEAN Member Country Regulatory Authorities for cross fertilization.

- Raise stakeholder awareness and need for increased transparency
  - Appeal for a more comprehensive representation of the SME and MNCs industry in the Medical Device trade associations
    - Not much information is available on the ASEAN Secretariat website.
    - Review of the working group's website reveals only general information about the group's objectives but no details on the work or documents for public review and comment.
  - Increased transparency would lead to champion the goal of harmonization and integration.

OBSERVATION AND RECOMMENDATIONS

- Need for uniform standards
  - As in the case for pharmaceutical products, there should be uniform recognized lists of Standards to be adopted all across ASEAN.

- Increase commitments in services
  - Permit the free flow of services within ASEAN. Although ASEAN Member Countries recognize the need to further liberalize healthcare services, commitments in schedules of the ASEAN Framework Agreement on Services (AFAS) have been limited due to country specific legislations.

- Intra-regional trade would benefit from non-restrictive rules of origin
  - To foster trade within the region ASEAN authorities should ensure that the rules of origin are not too restrictive, thereby allowing traders to access ASEAN Free Trade Agreement (AFTA) tariff preferences.

OBSERVATION AND RECOMMENDATIONS

- Encourage ASEAN collaborative efforts and protection of intellectual property rights
  - Medical Devices should be allowed to be traded freely within ASEAN if they meet ASEAN standards.
  - Countries should focus on specialized areas where they might have competitive advantage and procedures should be urged to apply for protection of the intellectual property rights (IPR)

- Step up post-market surveillance
  - There is an urgent need to improve post-market surveillance. The products/service liability requirements, such as traceability measures, are an issues that need to be taken into account in post-market surveillance.

STRIKING THE RIGHT BALANCE

- A higher level of safety assurance for consumers, regardless of where products are manufactured.
- Broader and quicker consumers access to innovative technologies
- Potential cost and time savings.


"We believe that common development is an important way to redressing global development imbalances and achieving sustainable development." -- Hu
Thank You