



**KEYNOTE ADDRESS  
THE OPENING OF  
THE 16<sup>th</sup> ASIAN HARMONIZATION  
WORKING PARTY MEETING  
NUSA DUA, 11 NOVEMBER 2011**

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Warm welcome to all speakers  
and participants



- To materialize accessible good quality healthcare for the community ➡ **Millennium Development Goals** or **MDGs** by 2015:
  - halve the numbers of people suffering from extreme poverty and hunger,
  - guarantee primary education for all children,
  - reduce by two-thirds the under five years old mortality rate,
  - improve the maternal health,
  - combat HIV/AIDS, Malaria and other diseases,
  - and to halve the proportion of the population without sustainable access to safe drinking water and basic sanitation



- **MDGs** ➡ certainly can only be achieved by providing comprehensive health care - from basic to referral health care
- Good quality health care must be supported by good quality, safe, and effective medical devices with their performance correspond to their functions
- The Government of Indonesia has also adopted an approach to safeguard good quality public health services by monitoring the distribution and use of medical devices



- Indonesian Constitution mandates that health and health care are the fundamental rights in the life of every Indonesian citizen
- Law Number 36 of 2009 on Health ➡ stipulates the importance of public-private partnerships
- the Presidential Regulation Number 5 (2010) ➡ regulates that improvement of human health resources to ensure community access to quality health care have to be carried out



- Rapid development in health technologies
  - ➡ higher cost of investment and operation
  - ➡ higher cost of health care
- Develop appropriate technologies: safe, effective and efficient, and of good quality, also accessible to all segments of the community
- Conduct ***Health Technology Assessment*** or ***HTA*** to examine the existing health technologies in a comprehensive and structured way



- The medical device industry is one of the most vital and dynamic sectors of the economy
- WHO → revenue from sales of medical devices worldwide was estimated at over US\$ 210 billion for 2008 → double the estimated revenue for 2001 → annual growth rate of about 6 %



- Medical devices cover a vast range of equipment, essential for patient. There is evidence that scalpel, slings, splints, crutches and other medical devices have been used since as early as 7000 BC by the Egyptians





- 1980's ➡ there was a surge in the number of patient care medical devices, in particular ***high-resolution imaging devices***, notably ***radiographic*** and ***fluoroscopic*** units
- Systems for continuous monitoring of ***cardiovascular parameters***—were becoming standard hospital fixtures



- 1980's – 2000's → most hospitals in industrialized countries adopted ***computerized axial tomography*** or ***CT*** scanners and ***magnetic resonance imaging*** or ***MRI*** units, ***robotics*** became a reality of the medical device world with proponents and opponents



- Future trend, smaller and less expensive robotic systems that allow high-precision surgery will continue to be developed, notably for orthopaedic and neurological procedures
- ***Nanotechnology*** and ***genomics*** will interact to continue the rise in personalized care



- It is compulsory to have a monitoring or protection system for the distribution of medical devices → majority of medical devices available in Indonesia are imported → the regulatory system needs to be closely supervised
- Indonesian medical devices regulatory control: pre-market and post-market control → law Number 36 of 2009 On Health
- The Ministry of Health of Indonesia → responsible for the safety, quality and efficacy of medical devices distributed and used in Indonesia



- The pre-market control:
  - manufacturing and production certification,
  - marketing licensing assessment,
  - product dealers licensing
- The post-market control ➡ post-market surveillance
- The Ministry of Health acts as a regulator to conduct the pre-market and post-market control



- To work towards medical devices regulations development, Indonesia actively participates in organizations :
  - ***Asian Harmonization Working Party*** → to study and recommend ways to harmonize medical device regulations in Asia and other regions
  - ***Global Harmonization Task Force,***
  - ***APEC,***
  - & other related international organizations → establishing harmonized requirements, procedures and standards



Indonesia will be able to prepare its medical devices control system to be harmonized with the control system in the Asian region



- As ASEAN member countries → actively involved in **ACCSQ-MDPWG** → formed following the **ASEAN Concord II** or **Bali Concord II** (Bali, October 7<sup>th</sup>, 2003) → agreed upon to enhance integration and economic relationships among ASEAN countries with a goal to form an **ASEAN Economic Community** which will make ASEAN **a single market and production base**



- Mandated by the **ACCSQ-MDPWG** → all member countries of ASEAN will follow the ***ASEAN Medical Devices Directives*** or ***AMDD***
- One of the directives includes the usage of ***Common Submission Dossier Template*** or ***CSDT format and Quality System*** based on ***ISO 13485***





- The medical devices harmonization within ***ASEAN countries*** and ***Asian countries*** aims at encouraging the local medical devices to be able to compete in the free-trade era
- Improvements in quality standard for medical devices → Asian products are expected to be accepted and recognized by the international market



- Harmonization of medical devices regulation in ASEAN as well as in Asian region should always benefit the interest of a wider public health beneficiaries
- As regulators, it is our duty to ensure that safety, quality, efficacy, performance, and affordability of medical devices must act as the benchmarks in the effort in improving the community health status



- Highly appreciate the efforts done by the Asian Harmonization Working Party to organize this meeting in Indonesia
- Declaring the ***16<sup>th</sup> Asian Harmonization Working Party Meeting*** officially open



***THANK YOU***