

Possible Future Areas for Cooperation Under ASEAN

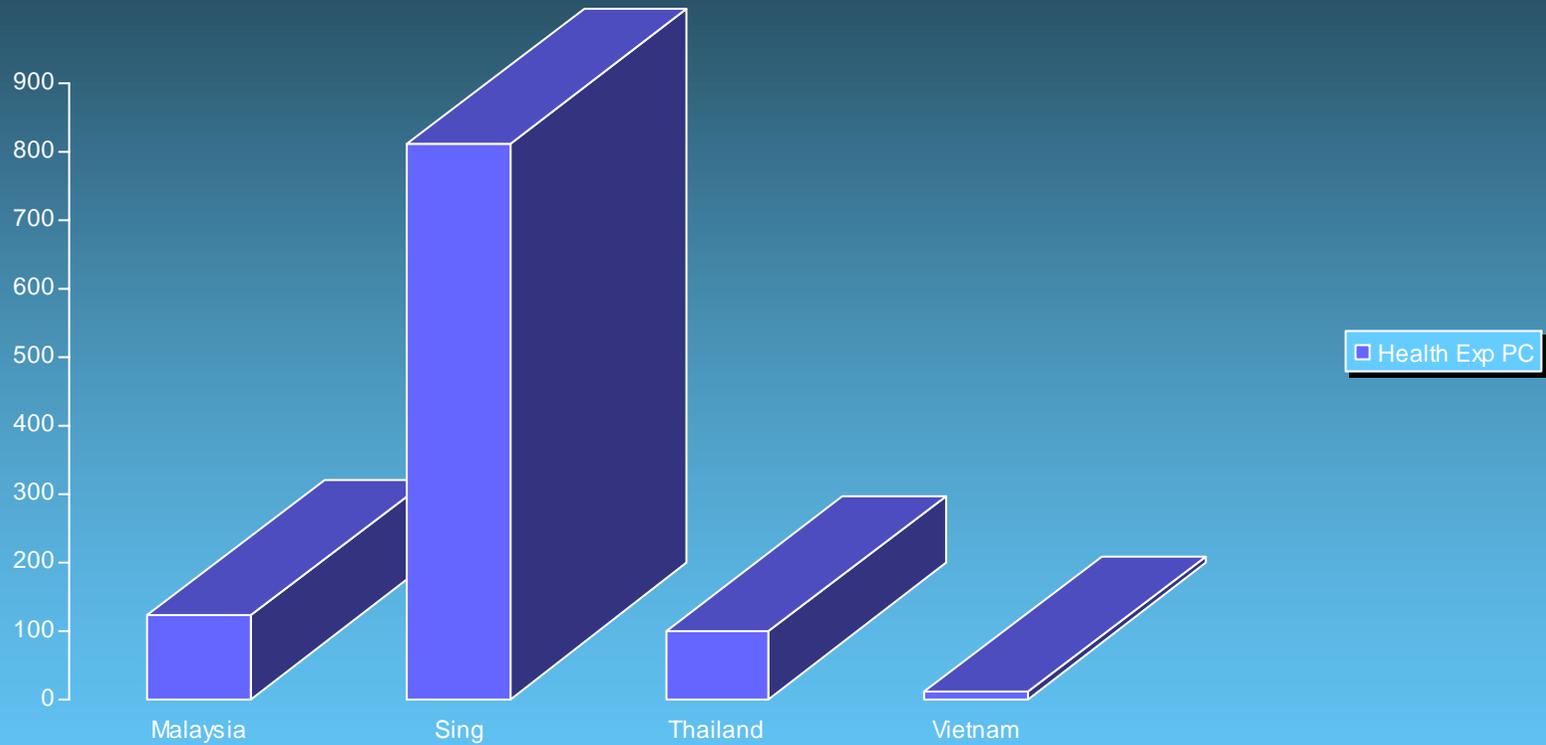
- * Enhanced Partnership Relating to Medical Devices Technology to Diagnose and Treat Primary Diseases/Infections, Pandemics, and Chronic Illness

Topics

- ASEAN Medical Devices Market Characteristics
- Key Objectives
- Ensure that Innovations Reach The ASEAN Community
- Technology Transfer and development
- Summary

ASEAN Market Characteristic

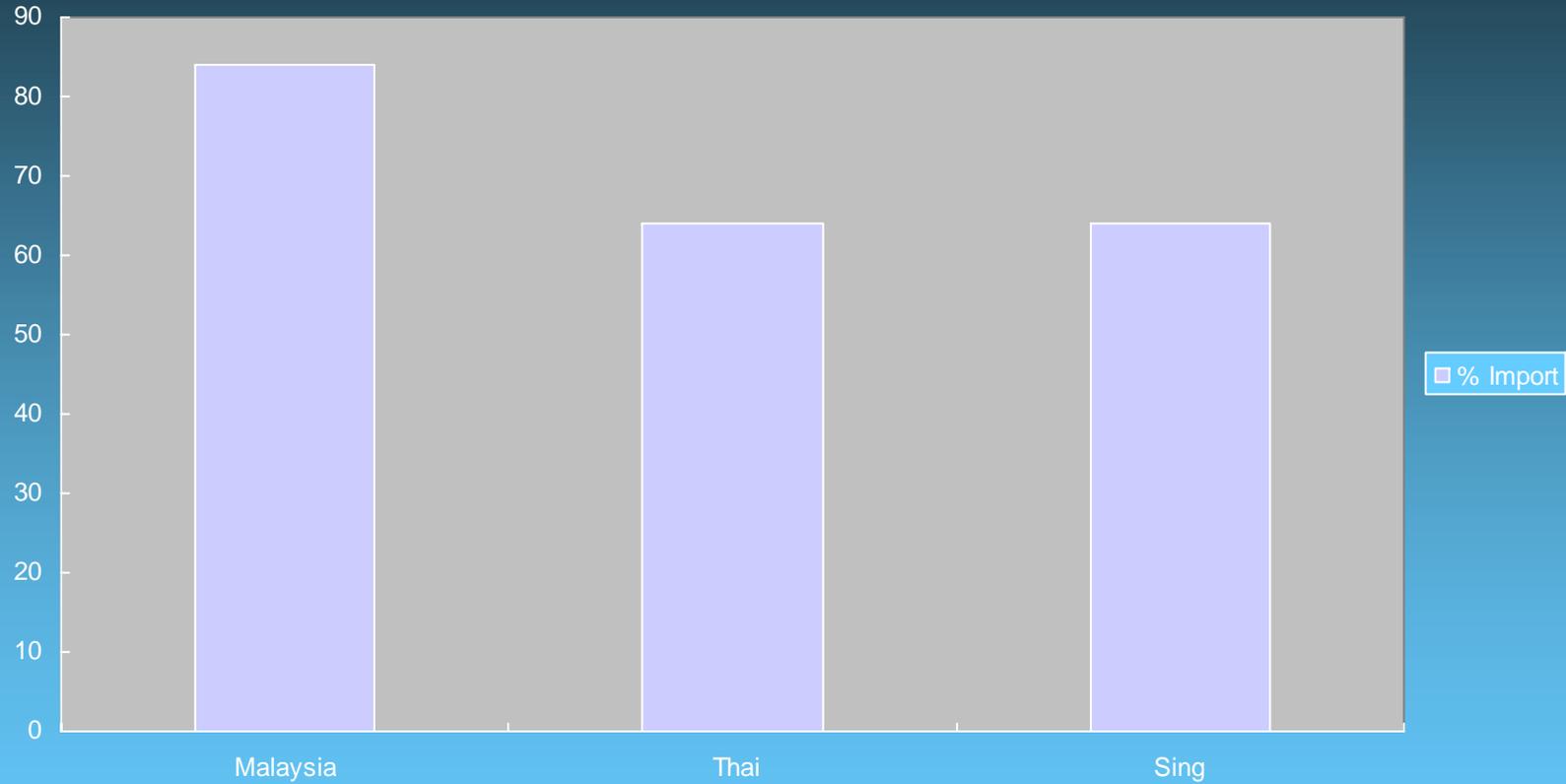
Per Capita Health Expenditures – Selected ASEAN Countries (\$US)



7/16/2007

Source: **Epicom Business Intelligence**

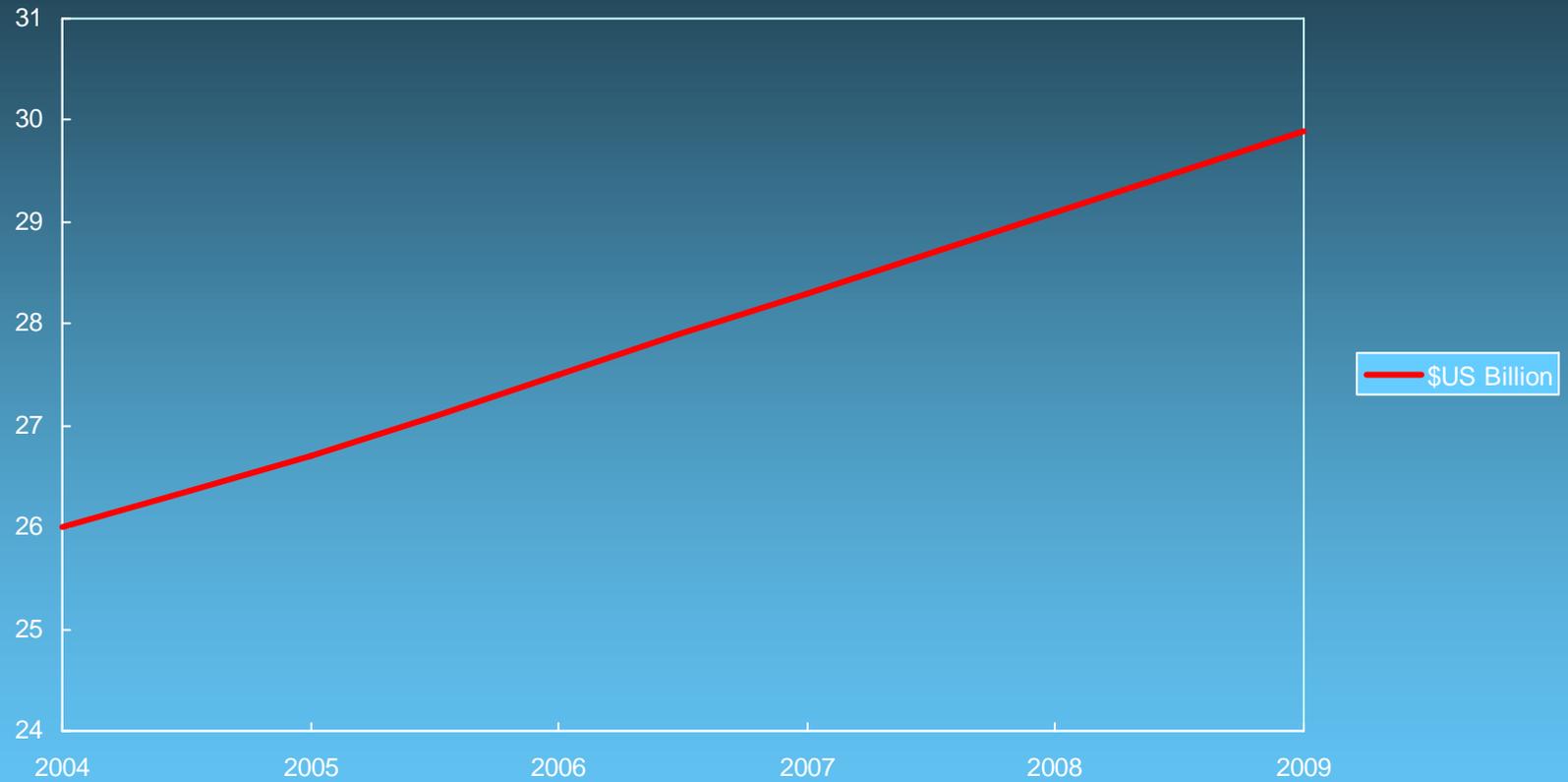
Imports – Percentage of Total Market For Selected Countries



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Source: Espicom Business Intelligence

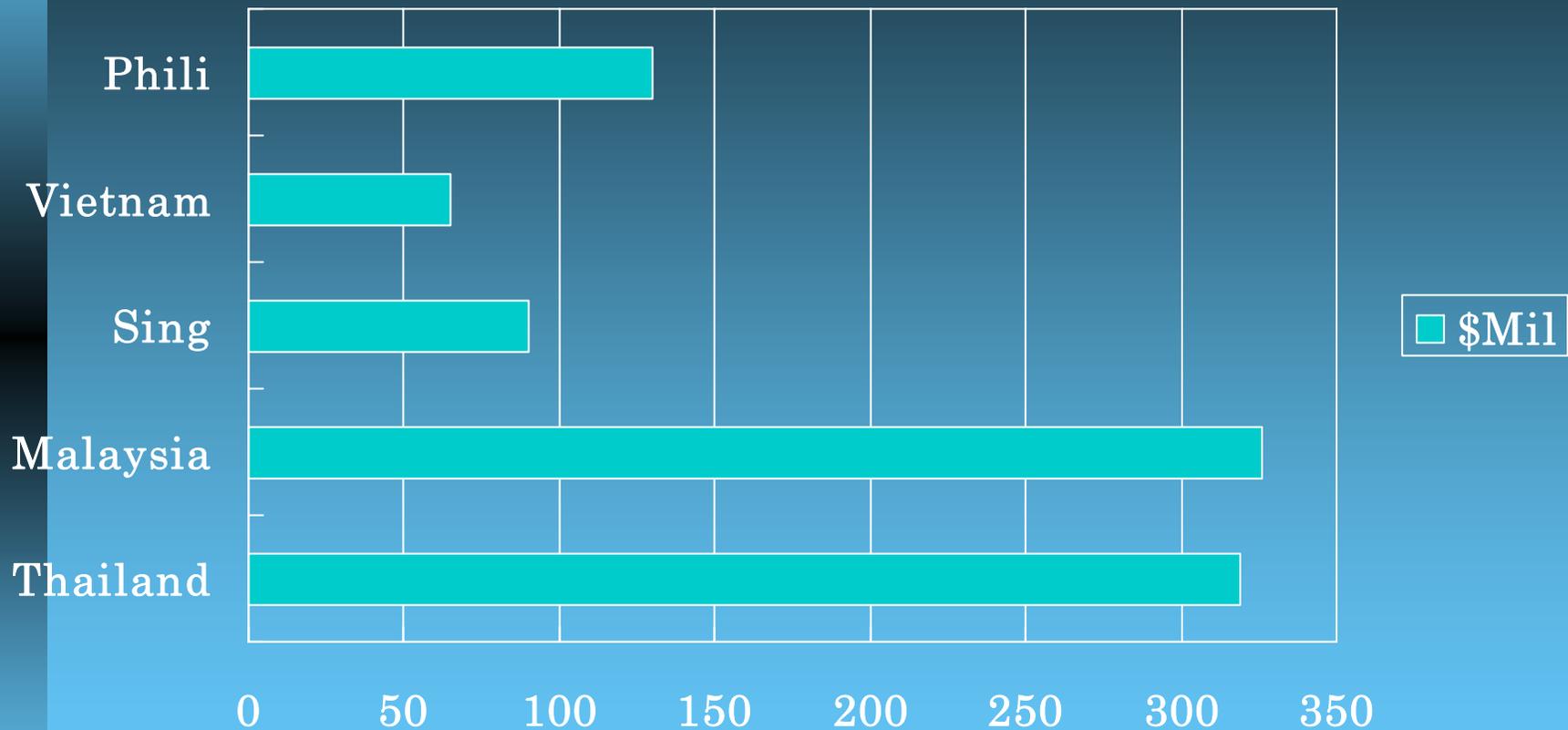
Projected Medical Device Market: Asia Pacific 2004-2009



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Source: **Espicom Business Intelligence**

Medical Device Markets in Asia Pacific (\$Million)



7/16/2007

Source: Espicom Business Intelligence

Key Objectives

Enhanced Partnership Relating to Medical
Devices Technology to Diagnose and Treat
Primary Diseases/Infections, Pandemics, and
Chronic Illness

Key Objectives

- Ensure that Innovations Reach The ASEAN Community
- Technology Transfer and development

Ensure that Innovations Reach The ASEAN Community

Background

- According to the WHO, approximately 1/3 of the world's population (between 1.3 and 2.1 billion people) lack access to essential medicines and proper medical treatment.
- Poor people die all the time from diseases that are preventable and curable.
- Increased international travel means our healthcare systems are inescapably interconnected.

Factors Associated with Access to Healthcare

- Regulation
- Financing Health Care
- Patent protection and IPR
- Tariffs

Regulation

Common Goals in Regulation

Many countries in ASEAN have set up their own systems for the control of medical devices. While they have a common goal to ensure the **quality, safety and effectiveness** of medical devices, their approaches of control differ.

Inappropriate Use of Medical-Device Regulations

- Save money by delaying approval of safe, advanced medical technologies
- Generate revenue through excessive fees
- Create jobs by requiring redundant local testing, reviews, and registration procedures
- Protect local industry by blocking approval of foreign products
- Delay improvements to vital healthcare infrastructure
- Increase cost of medical products and technology needed for hospitals, medical schools, clinics, and health services

MPWG Recommendation

Continue the effort to Integrate the Healthcare Industry

– Standards and Regulations

- Uniform procedures. The evaluation/approval process used by each ASEAN country should be similar. The Harmonised Cosmetic Regulatory Scheme is good illustration of this aim.
- Convergence of standards. The standards of each ASEAN country should ultimately converge toward a common international standard. This ensures that goods or services that are accepted by ASEAN countries would be accepted anywhere else in the world.

MPWG Recommendation (cont)

- Recognition of prior regulatory approval from benchmarked countries.
 - ◆ Approvals granted by a competent and qualified regulatory body (European Agency for the Evaluation of Medicinal Products (EMA), US FDA)
 - ◆ national certification bodies in ASEAN that have achieved similar standards as the bodies in these developed nations.
 - ◆ Once granted approval ASEAN countries should conduct an abridged approval process
 - ◆ This would reduce the need for wasteful re-evaluation or testing of new medical devices.



Don't
Reinvent
The wheel!!

GHTF Recommendation

- A post-market surveillance system be set up for medical devices in ASEAN. The system should aims to collect data on the performance and safety of selected high-risk devices on the market so that precautionary measures can be taken to minimize any potential public health risk associated with their use.

Financing Health Care

The Drivers of Health Care Expenditure

- **Demographics**
 - Less of an issue than often thought?
- **Changing epidemiology**
 - Rising burden of chronic disease
- **Advances in medical technology**
 - Can be both cost increasing and cost saving
- **Rising input costs**
 - e.g. wage costs
- **Patient expectations**
 - Patients are more demanding
 - Defensive medicine

The Funding of Health Care

- **Health systems raise finance through several sources**
- **Mandatory contributions**
 - Tax
 - Social insurance
 - Private insurance
- **Voluntary contributions**
 - Private insurance
- Full coverage insurance or top-up insurance
 - Over-the-counter payments
- **Co-payments**
- **Many health systems are dominated by mandatory contributions, although in practice they all have a mixed base of funding**

ASEAN Reimbursement Policies & Market Access

- Every market has its own unique set of problems
- Limited transparent and inconsistent reimbursement system

Inappropriate Reimbursement Policies

Limit Advance Medical Technologies in the Market

- Discourage manufacturers of high technology medical products from entering certain markets because reimbursement rate is too low
- Discriminate against technological innovators by focusing on initial cost (and ignoring offsetting savings resulting from innovations)

Characteristics of Good Reimbursements Policies

- Have clear and transparent rules for decision-making
- Set reasonable timeframes for decisions
- Allow input from suppliers and developers in the decision-making process
- Are sensitive to the medical-innovation process

Patent protection and IPR

ASEAN IPRs Characteristics

- Divergences and convergences
 - ◆ Differences in level of IP development and education
 - ◆ Differences in legal system
 - ◆ Language
- Convergence
 - ◆ Features of IP laws
 - ◆ Language

Need of patent protection and IPR

- IPR and integral part of multi-trading system
- Building knowledge-based economies and are important for promoting economic growth by expanding investment opportunities, spurring innovation and facilitating the growth of creative industries, including small businesses.
- To enhance ASEAN trade and investment
- TRIPS-legislative action

Points of Consideration

- Strengthening Intellectual Property Rights Protection and Enforcement
 - ◆ Develop the legal framework to make the IP laws in ASEAN in line with at least TRIPs requirements
 - ◆ Improvement of the administration of IPR
 - ◆ Improvement of the enforcement of IPR
 - ◆ Raising awareness in the ASEAN region on the importance of IPR for the economic development of a country.

Tariffs

Impact on Tariffs

- Impede access to quality healthcare
- Increase the cost of healthcare
- Limit access to the most advanced technology.
- Hurt the sickest and poorest the most

UN Trade Statistics

- Subject to import tariffs:
 - ◆ \$23 billion in medical technology
 - ◆ \$33 billion in pharmaceutical trade

Points of Consideration

- Elimination of tariffs for medicines and medical devices
- Product coverage still open – items under discussion include finished pharmaceuticals and bulk compounds, medical equipment, diagnostic products, surgical and dental instruments, orthopedics, etc.
- Participation by a critical mass of WTO Members
- Longer staging of tariff reductions for developing countries

Technology Transfer and development

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Key Contributions

1. Sustainable Development
2. Human Resources Development

Sustainable Development

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ASEAN Characteristics

- Lack of necessary technologies & appropriate institutions and financial resources in developing countries

Enhanced Partnership Areas

- Identify and address enablers of investment in life sciences innovation in health systems in ASEAN
- Assess research capacities with a view to developing scientific exchanges
- Partnership in Training as a means of enhancing the region's leadership in life sciences innovation and assuring health and economic development.

Enhanced Partnership Areas (Cont)

- Developed countries assist developing countries to build up infrastructure to meet Institutes and Enterprises needs.
 - ◆ Ease of availability of research materials among the ASEAN members
 - ◆ A collaboration clinical trial in ASEAN countries
 - ◆ Availability of seed capital funds

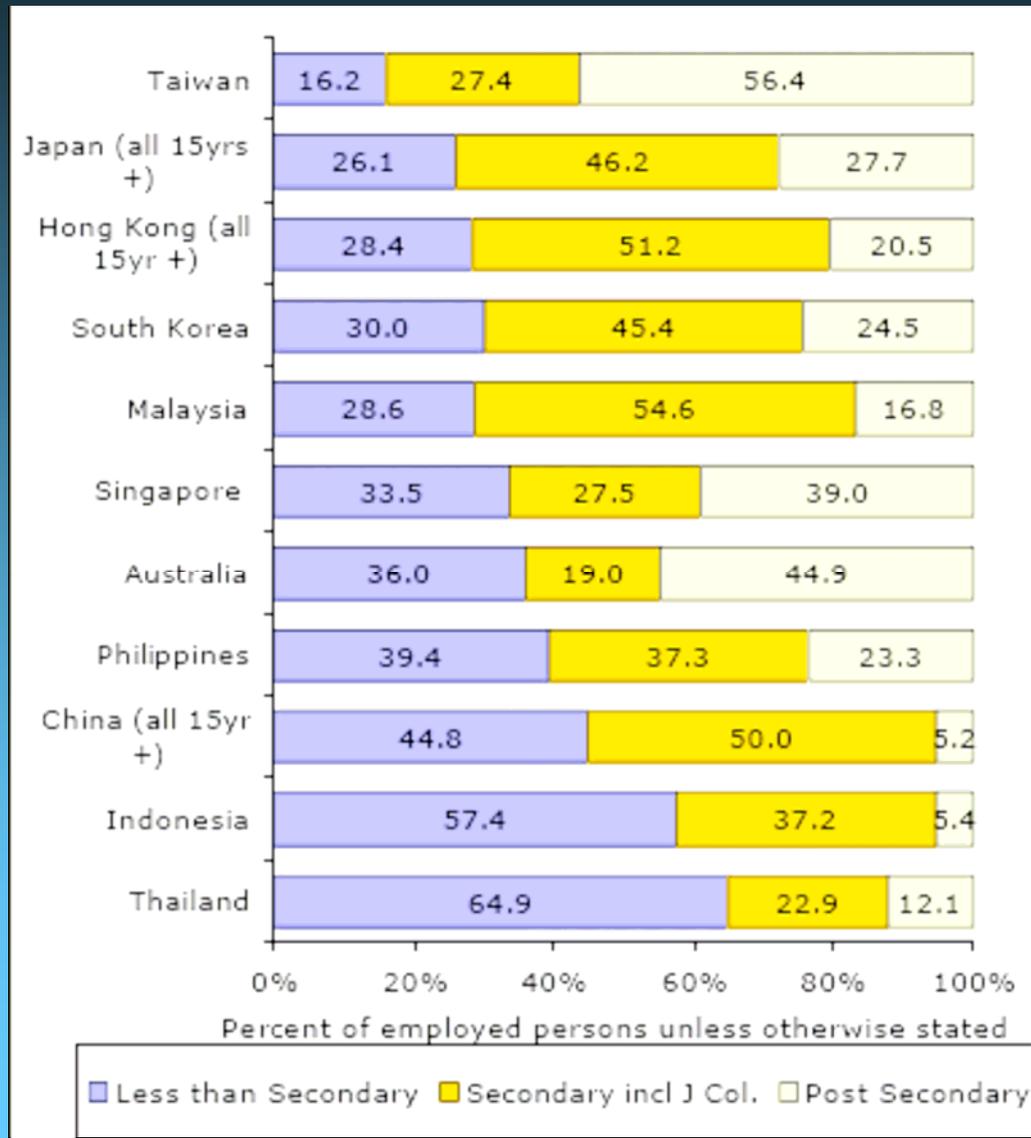
Human Resource Development

ASEAN Labor Characteristics

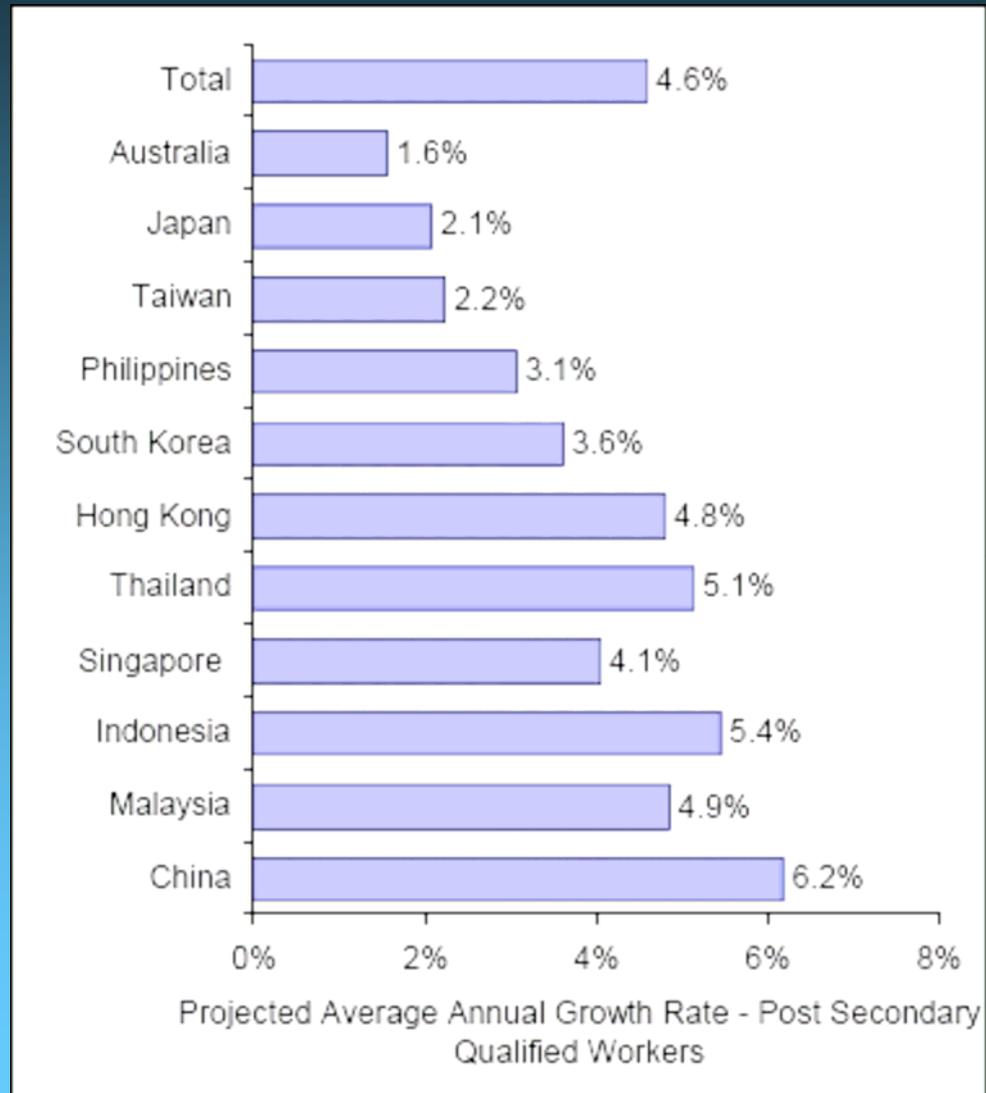
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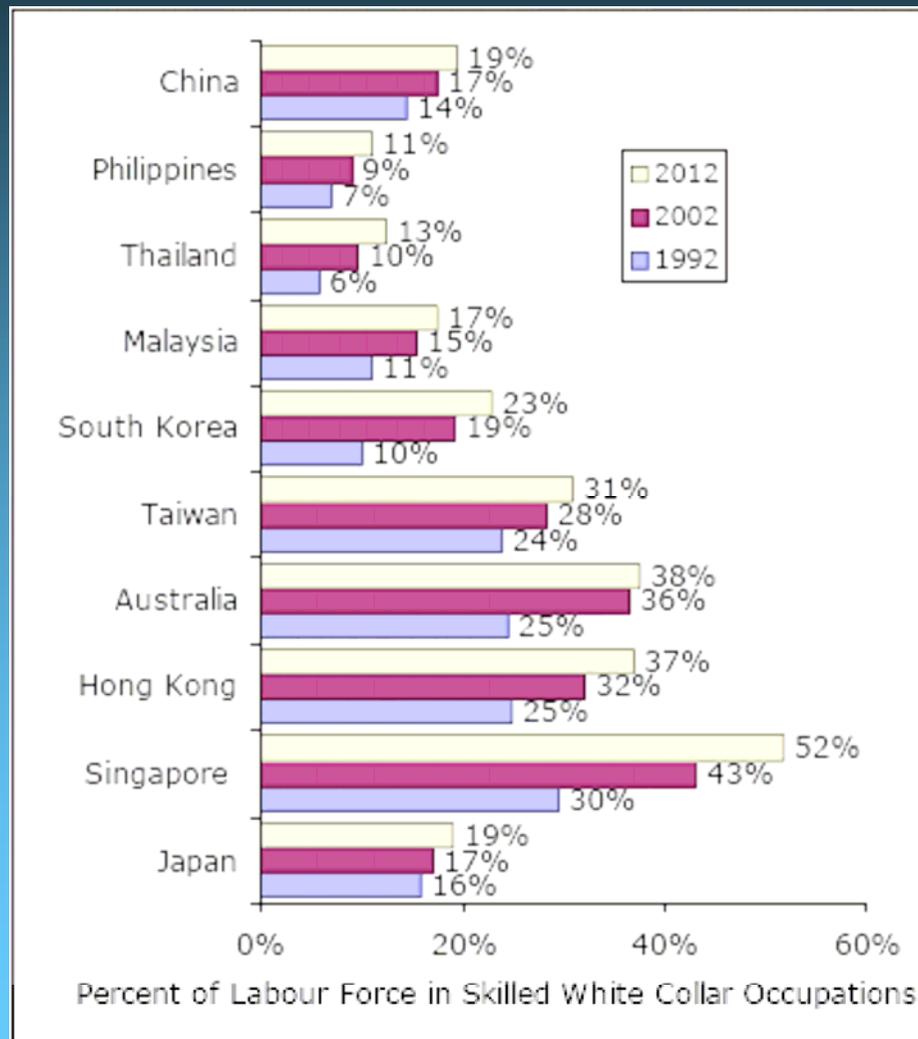
Education Profile of Employed (unless otherwise stated) Population by Country: 2002



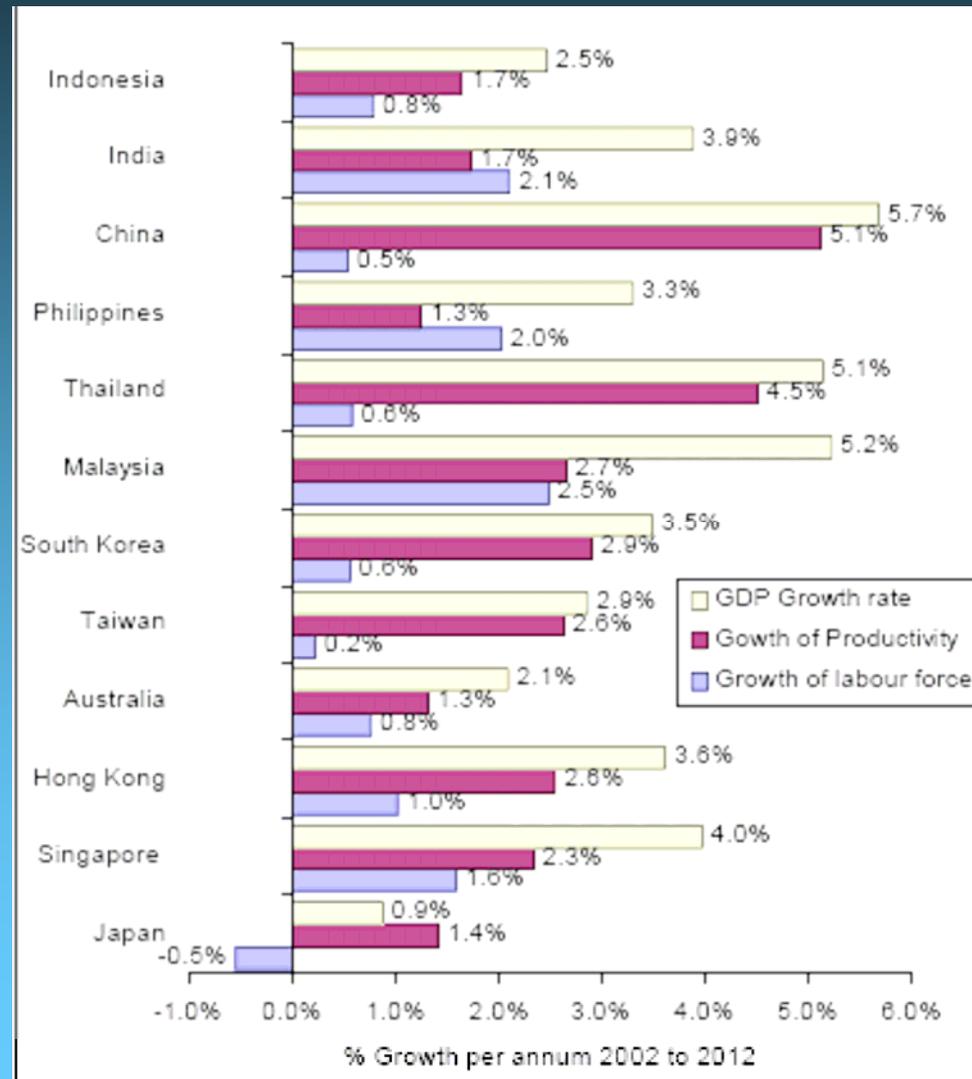
Projected Growth rate of Number of Post Secondary Educated Persons in the Labour Force: 2002 to 2012



Proportion of the Labor Force Employed in Skilled White Collar Occupations by Country: 1992, 2002 and 2012



Projected Growth rate per annum in the Labour Force, Productivity per Labour Unit and Real GDP for 2002 to 2012.



Enhanced Partnership Areas

Aim

To develop a workforce that has the skills and knowledge to undertake the technical transfer sustainable growth requirements.

- ◆ Identify of Healthcare technology skill needs both current and future including learning needs.

Summary

- There are numbers of opportunities to Enhanced Partnership Relating to Medical Devices Technology to Diagnose and Treat Primary Diseases/Infections, Pandemics, and Chronic Illness in ASEAN region.
- There are also a lot of Collaboration programs going on between ASEAN and other regions such as ASEM, APEC Life science innovation, JICA and etc. Therefore, a lot of overlap areas of collaboration and require strong coordinator to set up priorities need and resource allocation.

Our adventure journey just started!

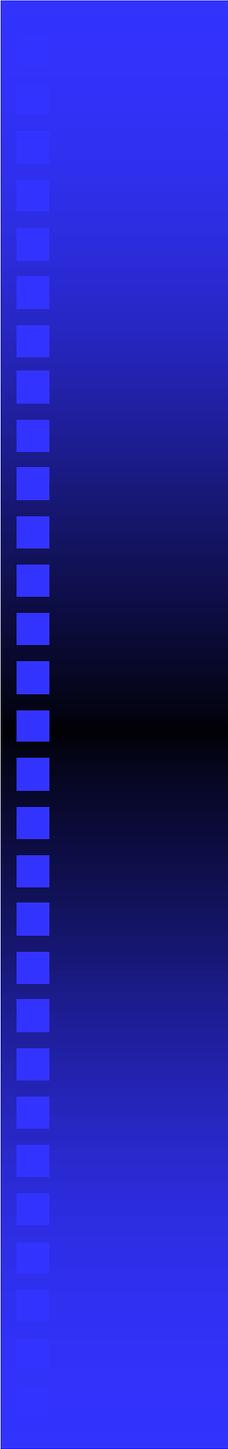


There will be a lot of challenges ahead of us!

Team work is very important!



We will reach our goal together!



Khop Khun Ka

Thank You