ASIA NOW: Navigating the ASEAN Region

Medical Equipment & Supplies

INDONESIA

Market Overview

- Forecasted growth rate of 15%
- Over 85% of medical equip. and supplies are imported – us$262 M (est.) in 2007
- U.S. import market share was 17% in 2007.

Best Prospects

- Electro-medical and diagnostic equipment
- Respiratory appliances
- Disposable products
- Surgical Instruments

PHILIPPINES

Market Overview

- Forecasted growth rate of 10% till 2008.
- Over 73% of medical equipment and supplies are imported.
- U.S. import market share was 25% in 2006.

Best Prospects

- Electromedical Equipment
- Ultrasonic Scanning Machines
- X-ray and Radiation Equipment

THAILAND

Market Overview

- Forecasted growth rate of 20% over 2007-2008.
- Imports account for 90 % of demand and totaled US$637 million in 2006
- U.S. led the imported market with a 34% share in 2006.

Best Prospects

- Heart valves & artificial blood vessels
- Implant devices
- Diagnostic testing devices
- Rehabilitation equipment

MALAYSIA

Market Overview

- Forecasted growth rate of 8-10%
- 90% of medical equip. & supplies are imported
- U.S. import market share was 26% of total 2006 imports

Best Prospects

- Electro-medical app.
- Orthopedic appliances
- Diagnostic & therapeutic radiation devices

SINGAPORE

Market Overview

- Forecasted growth rate of 4.5%-6.5%
- Over 80% of medical equip. & supplies are imported
- U.S. import market share was 25% of total imports

Best Prospects

- Health & cancer screening/diagnostics
- Disease management

VIETNAM

Market Overview

- Forecasted growth rate of 10% of medical equip.
- 90% of medical supplies are imported
- U.S. import market share was 30% of total imports in 2007

Best Prospects

- Imaging diagnostic equip.
- Operation theatre devices
- Laboratory Equip.

Pre-Market Approval Requirements

Most ASEAN nations require that imported medical products be registered through a duly appointed local agent or a distributor. Please view the below matrix for pre-market approval requirements for each ASEAN nation. The objective of this report is to assist the U.S. medical device industry in understanding the country's regulatory process in order to work more effectively with their import partners in gaining the necessary approvals.

	Indonesia 	Malaysia 	Philippines 
Governing Body	Directorate General of Pharmacy & Medical Devices Services, Ministry of Health	Ministry of Health	Department of Health
Local Clinical Trial Required	Yes, for some high risk products (i.e. in-vitro diagnostics).	No, though legislation is currently in the works.	Clinical trial for some high-risk products.
FDA Certificate of Foreign Gov. Required	Yes	FDA (US), CE (EU), TGA(Australia), TPP (Canada), MLHW (Japan)	Yes
Number of days for registration (from submission of data)	The standard administrative time clock for the approval process is three (3) months	Regulation is being drafted	Medical equipment is freely importable; but radiation-emitting devices need pre-registration.
Classification system of Medical Devices	Products are classified into three categories, low, middle and high risk.	Regulation is being drafted but at this point all medical devices except radiation emitting devices are freely imported	Products are classified into three categories -- low, middle and high risk.
Requirement for Market Clearance	Products must comply with regulatory provisions in the country of origin and meet the quality, safety and performance standards. Registration must be done by local agent/distributor. The agent/distributor must obtain license to import and distribute products from Ministry of Health.	Voluntary registration is on-going before full enforcement by 2008/09	Products must comply with regulatory provisions in the country of origin and meet the quality, safety and performance standards. An agent/distributor must have a license to operate as a medical equipment distributor and licensed to import such devices.
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Pre-Market Approval Requirements

	Singapore	Thailand	Vietnam
Governing Body	Ministry of Health, Health Sciences Authority's (HSA) Centre for Medical Device Regulation (CMDR)	Food and Drug Administration, Ministry of Public Health (MOPH)	Ministry of Health
Local Clinical Trial Required	No	No for General Devices (Class 3 by Thai FDA)	No
FDA Certificate of Foreign Gov. Required	FDA (U.S.), TGA (Australia) CE (E.U.), MLHW (Japan), TPP (Canada)	Yes	Yes
Number of days for registration (from submission of data)	8-10 weeks for evaluation of abridged submissions (products with prior regulatory approval)	15 to 30 days	15 working days
Classification system of Medical Devices	Aligned to International Best Practices. Adopt Regulatory Principles endorsed by the Global Harmonization Task Force (GHTF). Adopts a Risk-based classification – 4 classes, Class A (lower-risk) to Class D (higher risks)	3 Classes Class 1- requires MOPH authorization – HIV Kits, Syringes Class 2 – requires a notification to MOPH – Rehab Equipment Class 3 – Other General Devices – Certificate to Foreign Government	None
Requirement for Market Clearance	Registration must be done through locally set-up company or through a local agent/distributor. Phased Implementation of Medical Device Regulation beginning Nov 1, 2007 with Full Implementation by Oct 1, 2010.	None	Sale must be done by local agent/distributor that holds a license to import products. Import of used and refurbished equipment is not allowed.
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