



2016 Top Markets Report **Medical Devices** Country Case Study

Malaysia

Malaysia represents one of the more vigorous and vibrant medical device markets in Southeast Asia, presenting opportunities for U.S. exporters of medical technology to expand their sales into rising economies. Increasing patient access to healthcare will remain in the focus of the Government of Malaysia for the next five years, to include upgrading facilities and equipment, and expanding delivery systems.

Overall Rank

28

Malaysia's national healthcare expenditure historically is around 4 to 5 percent of GDP. In 2014, the Malaysian government set aside approximately \$5.83 billion, or 8.4 percent of the yearly national budget, for public healthcare. Out of this allocation, 7.5 percent is assigned for development purposes. Comparing public and private hospital expenditure, the public hospitals expenditure is about 65 percent while the private sector is around 35 percent. The number of hospital beds for both public and private healthcare combined has increased from 55,180 in 2010 to 58,530 in 2014. Public hospital beds accounted for 75 percent of total hospital beds in 2014.

Total two-way trade for Malaysia's medical device industry for 2014 is \$1.98 billion. Malaysian imports of medical, surgical, dental and veterinary science instruments and devices amounted to \$735 million. Singapore (27 percent) is the highest supplier to Malaysia. This is followed by the United States (19 percent), Germany (13 percent), Japan (8 percent), China (7 percent) and South Korea (3 percent). Overall, Malaysian medical device imports increased 8 percent over 2013. It is also worthwhile to note that Singapore is a major trans-shipment point for the Association of South East Asian Nations (ASEAN) region.

Country Highlights

Capital: Kuala Lumpur

Population: 29.9 million

GDP (USD): 326.93 billion (2014)

Currency: Ringgit Malaysia (MYR)

Language: Bahasa Malaysia

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Exports for the same category of medical instruments and devices from Malaysia increased 24 percent to \$1.24 billion in 2014. Top export destinations for Malaysia in this sector are the United States (43 percent), Germany (14 percent), Japan (22 percent) and Singapore (12 percent). It is also interesting to note a marked increase in total trade between Malaysia and the Netherlands. Total bilateral trade between Malaysia and Netherlands is \$60 million for 2014, a 143 percent increase since 2013.

The Government of Malaysia designated the Medical Device Industries sector as high growth potential in its next five year strategic economic plan (2016–20),

also known as the 11th Malaysian Plan. According to the Malaysian Ministry of International Trade and Industry, from 2010 to 2014, foreign medical device industry investments into Malaysia totaled MYR 11 billion (\$2.9 billion) while domestic investments were MYR 1.2 billion (\$316 million).

Improving and achieving universal access to quality healthcare will be the focus of the Malaysian government for the next five years. The major thrusts will be in improving healthcare quality to underserved populations, as well as ensuring efficient and effective expansion of the healthcare delivery system. In addition to upgrading healthcare facilities, a government priority is to reduce communicable and non-communicable diseases (CD and NCD). E-Health Information and Communications Technology (ICT) strategy will be implemented concurrently to track and support these measures.

Market Entry

Many exporters designate a Malaysian-based trading company as their local sales agent responsible for handling customs clearance of imported goods, for dealing with established wholesalers and/or retailers, for marketing the product directly to major corporations or the government and for handling after-sales service. In some cases, especially when selling to the government, a Malaysian Bumiputra status distributor is required. The term Bumiputra refers to a Malaysian of Malay or indigenous racial origin.

The passing of Act 737 and Medical Device Regulations 2012 has changed the regulatory framework for Malaysia. Industry players intending to export to Malaysia now need to register their medical devices with the Malaysian Medical Device Authority. Pharmaceutical and health supplements registration is with the National Pharmaceutical Control Bureau.

Current Market Trends

Increasingly, more Malaysians are taking the approach of wellness and disease prevention rather than treatment. Food and vitamin supplements are seen as preventive measures towards maintaining optimal health. Basic vitamin and pro-vitamins, as well as natural and organic supplements, are gaining

popularity. The United States is the largest supplier of healthcare supplements to Malaysia. U.S. brands are both trusted and well received by local consumers.

As for dental market trends, we are seeing subspecialties in the area of orthodontics, implant and esthetic procedures increasingly being offered in private dental clinics. The United States is one of the leading suppliers of orthodontics products in Malaysia.

Private healthcare services in Malaysia are predominantly used by the upper-middle to affluent segment of the population. As per capita GDP rises, demand for private healthcare consumption is expected to increase in tandem. Health screening is increasingly popular. Medical aesthetics procedures are also gaining ground in Malaysia.

Similar to other increasingly affluent countries, non-communicable diseases, such as diabetes, high-blood pressure, cardiovascular disease, oncology cases and obesity, are on the rise in Malaysia.

Main Competitors

The main competitors for U.S. companies in the Malaysian market are from the EU countries of Germany, the Netherlands, United Kingdom and France. Japan, China and South Korea have a strong presence in the Malaysian market as well. As noted above, statistical data show that the Netherlands made strong inroads into the Malaysian market in 2014 for the medical device sector with 143 percent total bilateral trade growth over 2013.

Current Demand

Consolidation is the key word for public healthcare resources and facilities. The Malaysian government is taking steps to implement a hospital cluster concept in select locations. Hospitals within a similar geographic region will serve as one unit sharing assets, amenities and human resources. Additionally, existing healthcare facilities and assets will also be upgraded. Healthcare services to the rural and remote areas will be expanded via mobile healthcare teams and flying doctor services.

Implementation of the e-Health strategy will include incorporating existing information and communications systems into one system-wide module. This should improve health data

management and support research and development and commercialization initiatives.

Pre-hospital care, such as ambulance services and accidents/emergencies services, will also be a key focal area. Ideally, collaboration between private sector and non-governmental (NGO) ambulance service providers will improve response time and better resource utilization.

Demand for private healthcare has been increasing exponentially due to its speedy service delivery and quality healthcare. In 2013, private hospital outpatient attendance was 6.8 percent of overall outpatient care provided in-country. Private hospitals also command 32.2 percent of total hospital admissions. In 2013, approximately 25 percent of the doctors, 38 percent of dentists and 33 percent of pharmacists were in private practice.

Registration Process

The Malaysian Medical Device Act (Act 737) took effect in 2012. Related Regulations specify requirements and procedures to medical device registration, conformity assessment body (CAB) registration, establishment licensing, export permit and appeal.

The Regulations went into force on July 1, 2013. A transition period of two years for medical device registration and one year for establishment licensing was given to the industry before the Regulations were fully enforced. The Medical Device (Exemption) Order 2015 has extended the transition period of medical devices registration for another year, ending June 30, 2016.

Thereafter, all medical device manufacturers in Malaysia will need to register their medical devices with the Medical Device Authority. Importers and distributors will also need to obtain an establishment license to import and distribute medical devices locally in Malaysia.

Barriers

All foreign companies need to work with a Malaysian company that is registered with the Malaysian Ministry of Finance in order to bid for government tenders. Hence, most of the government tender

information available online is in the local language, Bahasa Malaysia.

The Malaysian government is actively promoting local manufacturing of generic drugs and medical devices. There are instances of government procurement favoring locally produced and manufactured drugs, products and equipment— even when the bidding foreign companies' pricing is far lower, and the products and equipment are of equal or superior quality.

Trade Events

SE-Asian Healthcare Show

April • Kuala Lumpur, Malaysia • abcex.com/usa One of the region's most established trade shows, covering the entire healthcare industry. Regional visitors include Singapore, Indonesia and other neighboring countries.

APHM International Healthcare Conference

June • Kuala Lumpur, Malaysia • aphmconferences.org The Association of Private Hospitals of Malaysia (APHM) annual conference and exhibition. A significant annual medical event.

Resources

Healthcare Procurement, moh.gov.my/english.php
Government Health Plans, rmk11.epu.gov.my/index.php/en