New Directive Set to Boost $400M Medical Device Market Opportunity in South East Asia

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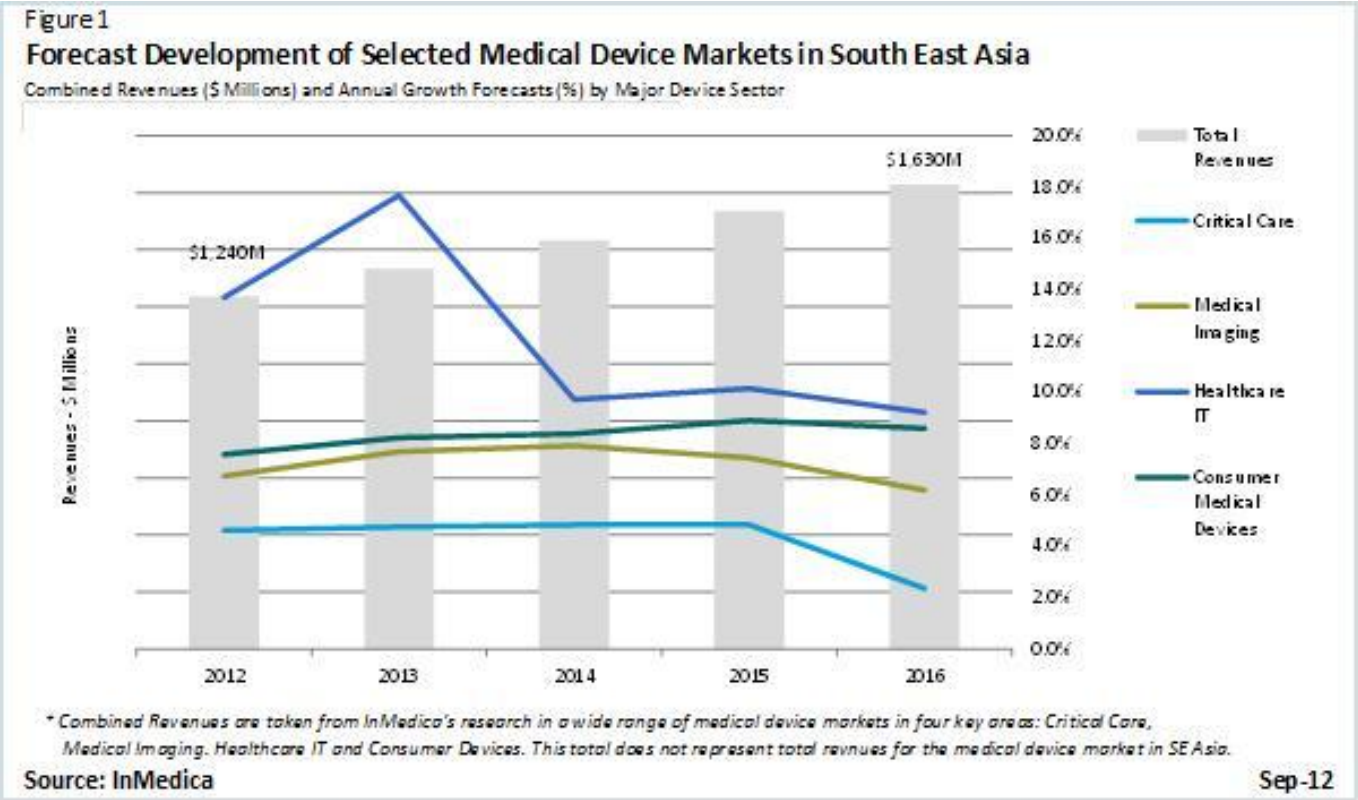
New ASEAN Medical Device Directive (AMDD) to ease market entry for international medical device suppliers

A new co-operation agreement between 10 South East Asia countries to standardize medical device registration will allow suppliers to take advantage of more than $400M of new emerging business in four key areas (medical imaging, clinical care, healthcare IT and consumer medical devices), according to InMedica, part of IHS.Inc (NYSE: IHS).

The syndicate of Association of South East Asian Nations (ASEAN) represents an addressable population of over 600 million (twice the population of the U.S.). With penetration of medical devices in this area is low compared to rapidly developing markets China and India, the potential for market development here is significant.

“Economic conditions and market saturation in mature healthcare markets are forcing major suppliers to explore new markets” commented Stephen Holloway, senior analyst at InMedica. “Complicated and varied device registration in such regions is one of the greatest barriers to market entry for international suppliers.”

Brazil is one such example of a market with great potential slowed by lengthy legislation processes. The stringent controls in Brazil often mean suppliers must extend ageing product lines or wait up to 18 months to market a new product. Simplification of this process if the AMDD is passed will allow quicker product introduction and investment in the ASEAN region’s developing medical device markets.



Supplier focus on developing markets has recently been evident with large-scale investment in manufacturing and sales force operations in regions such as China and India. Here, suppliers are manufacturing specific “value” products designed to address the needs of users in developing healthcare markets, in the country.

However, investment in operations and product development is just an initial step; long term barriers to growth in these regions still remain. The diverse range of culture, purchasing channels and languages makes it harder for suppliers from providing a direct “local” sales and operations force. Often, suppliers must partner with local distributors and suppliers, thereby losing control of how products are sold and gaining feedback from gaining direct customer feedback. Combined with public healthcare spending and investment levels below the global average, market development is not predicted to rival the explosive volume and scale of China.

“Initiatives such as the AMDD offer medical device suppliers one less barrier to market entry in the South East Asian region,” continued Holloway. “We project revenue growth of between 7 to 10 percent annually for the region based on current market conditions. If the AMDD is quickly implemented, the market has potential to double our forecast in the coming years.”

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