

"There are unlimited opportunities to transform healthcare in Asia"

01 August 2016 | Influencers | By BioSpectrum Bureau

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What are the expansion plans of Medtronic in Southeast Asia for next couple of years?

Like many parts of the world, healthcare in Southeast Asia, faces many challenges. The developed portions of Southeast Asia have an aging population with rising costs in a tight economy. The emerging portions of Southeast Asia face a higher demand for healthcare, but with inadequate infrastructure and clinical capability to serve the needs of the population. This places a heavy toll on patients and their families, as infrastructure development will take time to catch up with demand. At Medtronic, we recognize the constraints of the developed and emerging markets and are committed to improving patient outcomes, optimizing costs and expanding access to care to counter these growing demands.

With Singapore as our regional hub, we are well placed to play a central role in solving these issues. Our scale and breadth of resources now enhanced by the acquisition of Covidien, enables us to stretch further and reinforce our dedication to help lead a transformation in healthcare, not only across this region but throughout the world.

We believe that there are unlimited opportunities to transform healthcare in Southeast Asia. A key driver of our strategy focuses on instituting new ways of working and collaborating with like-minded partners. These approaches will help Medtronic to strengthen health systems and improve delivery of innovative treatments and therapies across the region.

For example, we recently signed two MOU's, one with National Neuroscience Institute to establish a Center of Excellence for

deep brain stimulation to advance treatment for patients with Parkinson's Disease, and another with SingHealth to set up a Center of Excellence in diabetes treatment and management in Southeast Asia. Through these efforts, we are educating physicians and patients about advanced life-enhancing technologies and therapies, while also working to make them more accessible in the region.

What is the share of business generated from Southeast Asia?

Southeast Asia represents an exciting, sustainable growth region for Medtronic. As part of the Asean Economic Community, this is a region that is getting better organized to capitalize on growth, with the region evolving from being the 7th largest world economy to expecting to become the 4th largest by 2030.

With over 650 million people, this region therefore has the potential to be in the Top 3-4 highest growth contributing regions.

Singapore considers med tech an important industry for economy growth. Are other Asian countries keen enough to invest in med tech sector?

In a McKinsey report in February 2016, it was reported that by 2020, Asia Pacific is expected to surpass the European Union as the world's second largest med-tech market after the United States. The demand for med tech in Asia Pacific is growing rapidly, and we anticipate that many Asian countries will continue to invest in this sector to address the growing demand for medical devices and patient needs.

How can new medical technologies revolutionize the healthcare system?

Asia Pacific, including Southeast Asia, faces serious healthcare challenges such as inefficient care delivery, rising costs, an aging population and the burden of chronic diseases, among others.

We are focused on helping patients with certain chronic and complex medical conditions, including but not limited to diabetes, stroke and coronary artery disease. We realized that these types of conditions are high volume, high cost, well-studied medical conditions and disease states with significant variation in treatment costs and outcomes. By focusing on them, these are the types of conditions that can result in meaningful improvements in cost and outcomes.

This is why, beyond focusing on developing technologies and services, Medtronic is looking at new ways and avenues to improve healthcare delivery and systems to drive better patient outcomes.

For example, by signing the MOU with SingHealth in June 2016, we hope to advance joint efforts to address the needs of people living with diabetes, especially in terms of developing and deploying innovative products and integrated solutions to improve quality of care and patient outcomes.

In 2011, Medtronic built a manufacturing facility to meet the expected growth in the demand of cardiac devices in the region. It allows us to respond more effectively and efficiently to the needs of customers and patients with cardiac rhythm disorders, improving standards of care in this region. We also built an education center to provide hands-on training for the latest technologies.

Can you share some new innovative products developed by Medtronic?

Medtronic strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

We have recently announced new results from the Medtronic Micra Transcatheter Pacing System (TPS) Global Clinical Trial in a late-breaking trial session in Europe.

The Micra TPS is less than one-tenth the size of traditional pacemakers and the only leadless pacemaker approved for use in both the U.S. and Europe. It is attached to the heart with small tines and delivers electrical impulses that pace the heart through an electrode at the end of the device. Unlike traditional pacemakers, the Micra TPS does not require leads or a surgical "pocket" under the skin, so potential sources of complications related to such leads and pocket are eliminated-as are any visible signs of the device. New clinical data continues to show the safety benefits of the Micra TPS for patients enrolled in the pre-market Micra TPS Global Clinical Trial.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias.

Can pharma and med tech companies work more closely to bring integrated products for healthcare?

In a region as diverse and complex as Southeast Asia, no single entity in the healthcare ecosystem can solve patients' challenges alone. Only by working together with a variety of stakeholders from academia, medical institutions and

government bodies, can we create far-reaching advancements in healthcare that patients around the world need and deserve.

How is regulatory in Southeast Asia evolving in the med tech sector in accordance to the new and innovative technologies?

ASEAN countries have come together as early as 2005 to form a Medical Device Product Working Group (MDPWG) and have developed a uniform system of registering and assessing medical devices across all member states. This is called ASEAN Medical Device Directive (AMDD) which was signed by the 10 member states in August 2014 and for transposition into their national regulations in January 2015. Thus, these member countries have started to draft, finalize and implement their medical device regulations in accordance to the provisions of AMDD. With the regulations being defined clearer and technical requirements being harmonized in the region, it is expected to have an increasing number of medical device companies entering into the ASEAN market with their most advanced and new generation medical technologies.

In 2015, this Medical Device Product Working Group had their last session and formed a new group called ASEAN Medical Technical Committee to discuss the detailed implementation plans of AMDD and challenges of each member country, to present new areas of discussion (e.g. refurbishment, medical device nomenclature) and to obtain technical assistance with dialogue partners. With the continued capacity building program for both ASEAN regulators and industry to support the implementation of the AMDD under the ASEAN-US Enhanced Partnership, it is expected that efficiency and proficiency shall be achieved in the assessment of medical devices, thus ensures faster registration approval for ASEAN countries resulting to faster and greater access to new technologies.

Is Southeast Asia an important region for clinical trial of new technologies?

Most definitely! Southeast Asia has over 650 million people and is a region that is fast growing in numbers and wealth and an aging population.

We know that many conditions such as vascular diseases manifest themselves differently in this part of the world due to a variety of factors, including anatomy, disease progression, patient age, lifestyle choices (nutrition, compliance, etc.). So there are important clinical insights we could obtain here that are not available from Europe or the US and that will enable better product development, treatment and diagnosis protocols that are better suited for the Asian population. In fact, because European or US data does not apply to Southeast Asia, it has slowed down the adoption of new technologies.

The collection of local clinical data itself is a powerful tool to raise disease awareness among governments and make stronger reimbursement arguments that open up access to care for more patients. In Southeast Asia, Singapore is a great market for trials and registries because of its infrastructure and credibility around executing high quality research. We also have the advantage that we have so many regional ethnicities. Thailand also has good potential for research given their bigger population base, physician skill, comparatively good infrastructure, and more reimbursement which provides for greater access to care.

What are the challenges of conducting clinical trials in Asia?

The main challenges are around experience in conducting clinical research, access to enough (paying) patients in some markets, and infrastructure in some countries. The competition among centers to become part of research efforts or the disappointment of not being selected is stronger here than in more mature markets where certain therapies are more broadly adopted. There is also less experience in writing peer-reviewed articles and conducting the analysis. This means that we either need to pair centers up with Western KOLs to write the articles or we need to invest in providing training for this. Writing these articles is difficult and requires a lot of experience. I have had numerous discussions about this with Western KOLs who had SEA physicians attached to them and most felt that research and writing experience is lacking. This is partly due to language barriers and partly to a predominant focus on clinical practice versus research, which is very understandable. This also closes the door on access to premium journals, which Medtronic and Western KOLs can help with.