McKinsey&Company

MedTech in Asia
Committing at scale to raise standards of care for patients

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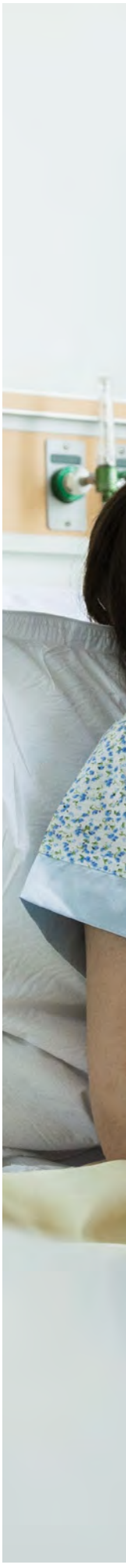
MedTech companies have approached Asia-Pacific's diverse and volatile markets cautiously. The region's underserved patients deserve a greater commitment.



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This work would not have been possible without the support of APACMed's member companies, which contributed expertise, data, and examples of their impact in the region. During our half-year research, we collected data from 30 leading MedTech companies in the region and input from around 150 senior executives.

We also interviewed numerous representatives across important healthcare stakeholder groups, including healthcare providers, payers, academic researchers, regulators, and representatives from other relevant government agencies, as well as other MedTech industry associations. We are grateful for the time they committed to helping us and the perspectives they shared.

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Executive Summary

The need for healthcare in the Asia-Pacific region is rising quickly. The region is home to more than half of the world's population, and facing a rapidly growing disease burden from aging and lifestyle changes. Expanding incomes and broader awareness of health issues are also contributing to this picture, and healthcare demand will continue to outstrip supply for the foreseeable future.

Although medical technology companies have been active in the region for many years, helping to raise healthcare standards, they face numerous obstacles as they seek to serve a bigger pool of patients. These obstacles are unlikely to fade anytime soon; accordingly, MedTech companies must adapt to meet the complexities presented by the region. Successful companies will help address a broader range of the region's healthcare needs, at the same time securing a leading position in what is poised to become the second-largest market for MedTech.

With the support of the Asia Pacific Medical Technology Association (APACMed), McKinsey & Company has examined and analyzed the opportunities and obstacles facing the industry in the region. As part of the research, we interviewed and surveyed some 150 executives from 30 leading MedTech companies active in Asia-Pacific. In addition, we assembled case studies to help identify the best practices and measures companies have taken to bring medical technology to a wider range of patients in the region.

This report presents some observations and conclusions from our research:

- **Asia-Pacific presents a diverse collection of markets with significant unmet healthcare needs and attractive growth potential.** The medical needs in Asia-Pacific are vast and spread across different countries, cultures, and development levels. The diversity in demographics, disease profiles, healthcare systems, and regulatory regimes presents big challenges. At the same time, surmounting these hurdles offers an unparalleled opportunity to pursue innovative products and services that could not only meet the needs of patients in Asia-Pacific, but globally.

- **Obstacles specific to the MedTech industry have hindered its reach in the region.** The MedTech industry has traditionally focused on the premium segment and not yet penetrated Asia-Pacific as fully as many other industries have. Along with a generally cautious approach to the region, MedTech companies have been hindered by specific obstacles:

  — limited financial resources and a frugal attitude toward spending on healthcare
  — multiple customer segments that are difficult to serve efficiently
  — underdeveloped medical infrastructure and workforce, which inhibits the adoption and use of new technology
  — a fragmented and inconsistent set of regulatory and reimbursement regimes that serve as a deterrent to introducing new technology
  — intense competition from regional start-ups, as well as increasingly from global leaders in adjacent industries, such as high tech and consumer electronics

- **Beyond traditional market development activities, MedTech companies can take measures to overcome these challenges and broaden their reach.** To move beyond the premium segment and reach a broader group of patients and healthcare providers, MedTech companies should focus on three themes:

  — rethink business models and channels that lean too heavily on tiered distributor networks; create closer links with end users; and develop clearer insights into their needs
  — review offerings and develop market-appropriate products and services rooted in innovation that appeal to customers seeking different value propositions
  — ensure that organizations give sufficient autonomy to senior management in the region and adopt a long-term orientation in decision making and resource allocation

- **Fundamentally, greater collaboration among stakeholders could help remove some of the structural barriers.** Regulators, academics, healthcare providers, industry executives, trade groups, and patient groups should collaborate to reduce structural barriers. The study suggested three areas where industry-wide collaboration can have real impact:

  — building regulatory capacity and capability building, by partnering with academia to deliver programs for regulators and regulatory affairs professionals
  — using technology to accelerate and enhance medical education
  — driving shifts in the mindsets and behaviors that result in slow adoption of changes in technology and delivery models

Public and corporate leaders have already taken many steps to address these challenges but more can be done. On a more fundamental level, the region's underserved patients deserve a chance to access better healthcare.

Unmet needs in APAC

~3.7B people
51% of world's population lives in APAC

1.1B people
50+ years of age by 2025

65M babies
born each year (equivalent to UK population)

2B people
in consuming class by 2025 (~50% of whole APAC)

2/3 global disease burden
for major chronic respiratory diseases

APAC MedTech market, $B

Realities facing MedTech industry in APAC

Challenging and underserved market

Frugal spending
Average healthcare spend per capita

APAC	376
EU	4,018
US	9,146

22% of global MedTech market

VS

32% of global GDP

VS

51% of global population

Multi-segment markets
80% of emerging APAC population cannot afford MedTech solutions designed for developed markets

Regulatory complexity & under-capacity
China's regulatory staff workload 20X relative to the US

Inadequate infrastructure
India will take 85 years to achieve OECD physician density

Intense competition
10+ local Asian companies with MedTech revenues $1B+

Opportunities for industry-wide collaborations

Regulatory capacity
Partner with academia to expand pool of regulatory affairs professionals

Medical education
Use technology to enhance the pace and quality of medical education

New delivery paradigms
Accelerate adoption of new healthcare delivery models (e.g. homecare)

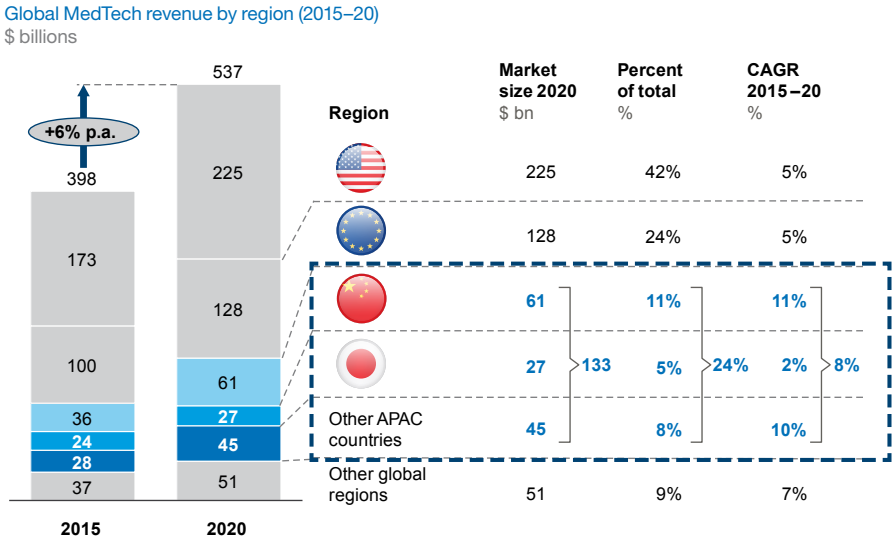
Introduction

Asia-Pacific is vast and varied with an extensive array of unmet patient needs. The region, ranging from the beaches of Australia to the deserts of China, is also a complex market. Medical technology companies that wait for an ideal situation before committing fully to Asia-Pacific will find themselves left behind as more decisive players move forward. Recent research and experience shows MedTech companies can take specific steps to capture this diverse market and better serve patients. In addition, industry stakeholders can work together to deliver improved healthcare across the region.

Demographics, health indicators, and continued economic growth in the region all provide attractive markets for MedTech companies. By 2020, Asia-Pacific is expected to pass the European Union as the world's second-largest MedTech market (Exhibit 1). Nevertheless, the industry has yet to engage in the region as heavily as many others have and, as a result, has failed to capture its full promise. While business opportunities have been missed, many patients are also not receiving optimal care.

Exhibit 1

APAC will outgrow the European Union to be the second-largest market for MedTech by 2020



SOURCE: Business Monitor International; GlobalData (Oct 2015); Health Research International 2015; McKinsey analysis

Throughout Asia-Pacific, national markets present a diverse mix of distinctive characteristics. Some now resemble Western markets, but many retain unique traits. At the same time, physician shortages trouble much of the region, and healthcare quality can vary, with providers in some regions having access to the latest equipment and procedures, while others are coping with more limited resources as best they can.

While business opportunities have been missed, many patients are also not receiving optimal care.

So far, most MedTech companies have made inroads into the region largely by catering to premium customers. To reach a much broader range of patients they will have to make improvements in three areas related to local adaptation: sustainable business models, market-appropriate products and services, and tailored organizational models. In addition, stakeholders—including government and business leaders, academics, healthcare providers, and trade groups—must come together to address structural obstacles, which have left many patient needs unfilled.

To help understand the obstacles and opportunities faced by MedTech companies, McKinsey worked with the Asia Pacific Medical Technology Association (APACMed), an industry association established in spring 2015, to look into the dynamics of the region. As part of the study, we interviewed or surveyed some 150 executives from 30 MedTech companies, as well as policy makers, providers, and regulators. We also developed dozens of case studies to help determine best practices in the region and identify clear examples of efforts that contribute to raising standards of care for patients.

Asia-Pacific demands attention

Asia-Pacific is home to more than half the global population; based on size alone, the region is both attractive and intimidating. Adding to the challenge, the region is far from homogenous, with dozens of different markets—even within a single country such as China or India—and each market showing unique characteristics. While other industries like high tech have navigated similar challenges in the region successfully, MedTech companies face specific obstacles that have resulted in slower progress.

Partly as a result of the region's complexities and also because of extensive opportunities elsewhere, leading MedTech companies have lagged behind other industries in serving the region, creating gaps in patient services and bypassing significant opportunities.

An unprecedented need…

The scope of patient needs in Asia-Pacific is unprecedented. More than 3.7 billion people live in Asia-Pacific, and by 2025 about a quarter of the region's population will be elderly. Each year about 65 million babies are born in Asia-Pacific. More than two-thirds of the

world's cities with more than 10 million people are in Asia-Pacific, and by 2025, more than 50% of the region, or 2 billion people, will be in the consuming class (Exhibit 2).

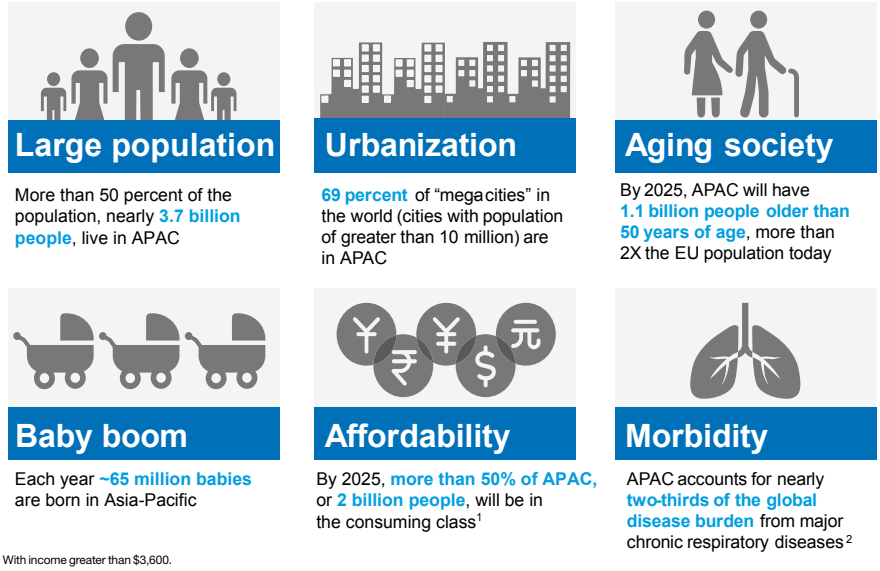
But the story goes well beyond demographic trends. For more than a decade, the global economic center of gravity has been sliding away from the developed Western economies and toward Asia-Pacific. The shift has been led mostly by China's rapid economic growth, but not exclusively. The region could account for 35 percent of the world's total GDP by 2020, from 25 percent in 2000, and be home to four of the world's top ten national economies.

In many Asia-Pacific countries, incomes are expanding rapidly and, although they remain low compared with those in more developed regions, many households are reaching income levels of at least $3,600 a year, an amount that covers basic necessities with sufficient discretionary income remaining to go toward healthcare. In Malaysia, for example, households with annual income of at least $3,600 comprised almost three-quarters of the population in 2012, and in Thailand, nearly half. In China, this consuming class accounted for a smaller share of the population, about 28 percent, but comprised nearly 400 million people, dwarfing the population of most countries.

The region's healthcare needs reflect its size. In 2015, for example, Asia-Pacific accounted for nearly two-thirds of the world's overall burden for chronic respiratory diseases, according to measures of disease-adjusted life years (DALY), and nearly half the world's burden of all critical and chronic diseases. By 2025, more than a billion people in the region will be older than 50, entering a life stage where medical needs increase sharply.

Exhibit 2

Significant needs and growing demand for healthcare in APAC



1 With income greater than $3,600.

2 Measured as disability-adjusted life years (DALYs) lost to COPD, asthma, and lung cancer.

SOURCE: IHS Economics (2015); World Bank; McKinsey Insights

A number of trends underpin the demand for improved healthcare in Asia-Pacific. Among these, many governments are thinking about instituting universal healthcare. Some private hospital chains are expanding rapidly, while new funding channels, such as private equity, are opening. Brisk innovation in healthcare delivery models also suggests a vibrant sector.

The market for MedTech in Asia-Pacific is estimated to have reached almost $90 billion in 2015, about a quarter of the global total. Growth is forecast to continue, with the Asia-Pacific market more than doubling over the next ten years to about $190 billion, potentially accounting for approximately a third of global sales. Growth rates for individual national markets will vary considerably, though.

Our survey of MedTech executives showed that respondents on average believe the market will expand by 8 percent annually over the next decade. Not surprisingly, most growth in absolute terms is expected to come from China, despite a recent moderation in growth rates from as high as 20 percent in some categories to around 10 percent for most companies. The markets in India and Southeast Asia are also expected to post significant growth in coming years, while Japan will grow at low single digits, from a large base.

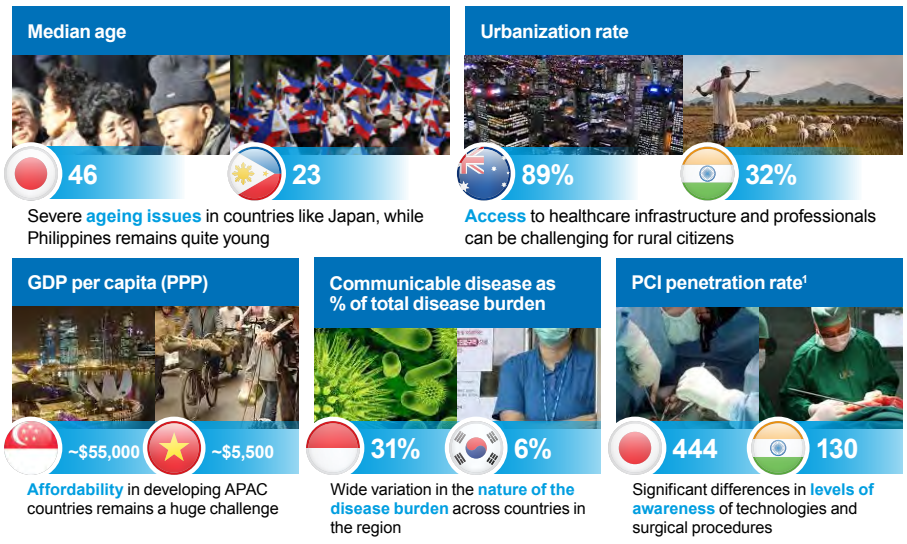
… and daunting complexity

Unlike the relatively cohesive markets of North America or Western Europe, Asia-Pacific is a compilation of diverse markets brought together more by proximity than anything else. It is governed by democracies, monarchies, and autocracies. Demographic metrics further reflect the extreme regional diversity (Exhibit 3):

- **Age:** Japan, with a median age of 46, has one of the world's oldest populations, while the Philippines, where the median age is 23, represents the opposite extreme.
- **Urbanization:** In Australia, 89 percent of the population lives in cities, compared with just 32 percent in India.

Exhibit 3

Wide diversity in the nature of healthcare demand within APAC markets



1 PCI (Percutaneous Coronary Intervention), # of cases per 100,000 population >50 years old.

SOURCE: GlobalData (Oct 2015); IHS Economics (2015); WHO; World Bank

- **Income:** Singapore's GDP per capita stands at $55,000, ten times that of Vietnam's $5,500.

Healthcare challenges also differ greatly. For example, communicable diseases account for 31 percent of the total disease burden in Indonesia and just 6 percent in South Korea. Infrastructure, access, and public outreach can vary widely as well, leading to differences in standards of care. In Japan in 2011, there were about 444 percutaneous coronary interventions per 100,000 people older than 50, almost four times the rate seen in India.

As might be expected, government approaches toward healthcare also diverge. Japan, New Zealand, and Thailand offer universal health coverage and government accounts for 80 percent or more of healthcare spending in these countries. At the other extreme, government outlays in India, Indonesia, and the Philippines cover less than 40 percent of total healthcare spending, although these countries also aspire to create universal healthcare systems and have taken steps in that direction.

National systems are also pursuing contrasting healthcare models. Some, like Australia, Singapore, South Korea, and Taiwan may be emulating or improving on Western models, while others are looking more toward local tradition and culture in their healthcare approaches. China, India, Indonesia, and the Philippines, for example, are establishing their own high standards for quality care.

Along with the potential for reaching underserved patients and participating in growth markets, Asia-Pacific offers other opportunities for MedTech companies. In particular, the region is likely to account for an increasing share of global innovation.

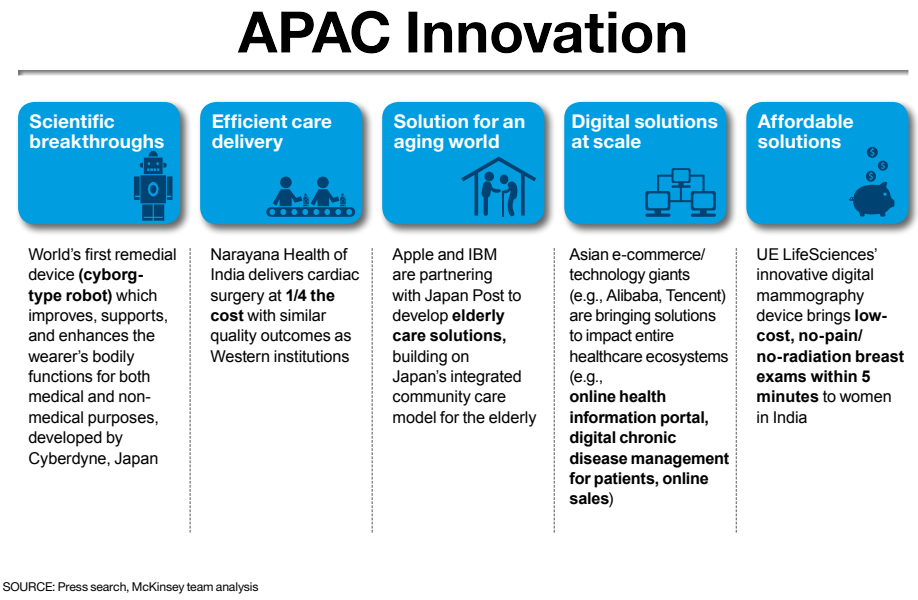
Adding to the complexities, the economies in Asia-Pacific are progressing at different rhythms. China, for example, has been the economic engine pulling Asia-Pacific forward for decades, but recently its slowing growth has caused concern regionally and globally. In the late 1990s, Southeast Asia, home of some of the fabled tiger economies, suffered a financial crisis that rocked confidence in that region. And after struggling to find its economic footing, India may finally be entering a growth spurt, while Japan continues to battle decades-long stagnation.

Beyond the numbers

Along with the potential for reaching underserved patients and participating in growth markets, Asia-Pacific offers other opportunities for MedTech companies. In particular, the region is likely to account for an increasing share of global innovation. In areas like digital healthcare delivery, care for the elderly, and products and services appropriate to frugal customer segments, innovation is needed to engage more broadly in Asia-Pacific. Already, global MedTech leaders are active in the region, broadening patient access to medical technologies as they expand their market.

Exhibit 4

Multiple opportunities for APAC to lead innovation for global healthcare



SOURCE: Press search, McKinsey team analysis

Some challenges in Asia-Pacific could also inspire innovation elsewhere in the world (Exhibit 4). For example, serving Japan's aging population has led to new models in integrated community care and experiments with care systems using robotic technology that could be applicable to other markets. Innovation in delivering low-cost, quality care could benefit other countries seeking to reduce healthcare spending. Tackling China's large and dispersed market could create models for building scale that could be replicated elsewhere.

Although the United States will remain the dominant market for MedTech companies for the foreseeable future, Asia-Pacific's expected economic growth, underserved patient needs, and its value as a test bed for innovation argue for a greater commitment to the region.

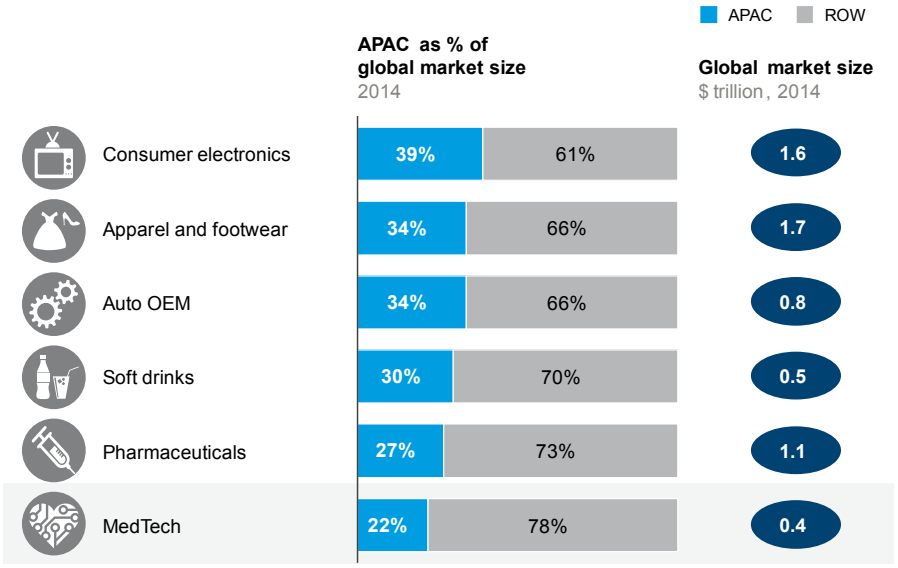
Realities facing the MedTech industry in Asia-Pacific

Without question, Asia-Pacific is a demanding region for business leaders, particularly compared with more developed and homogeneous markets, such as North America, where many business models were created and have evolved. Yet other industries have managed to capture a greater share of the region's potential than the MedTech industry (Exhibit 5).

In 2014, Asia-Pacific accounted for 39 percent of the $1.6 trillion global market for consumer electronics. The region also comprised just over a third of the global market for apparel and footwear and for new cars. In contrast, Asia-Pacific made up only about 22 percent of the global MedTech market, just behind pharmaceuticals. While MedTech is a much more regulated industry than others, which limits its share in Asia-Pacific, the MedTech market shows significant room for growth: the region has more than 50 percent of the world's population, more than 50 percent of the world's chronic disease burden and nearly 60 percent of the world's aging population. Even if the Asia-Pacific MedTech share continued to grow at current rates it would only reach about 27 percent in 2025.

Exhibit 5

APAC's share of the global revenue pool for MedTech lags other industries



SOURCE: Annual reports; BMI; Euromonitor International; HRI; IHS Automotive; IMS Health Incorporated

Work with MedTech companies and discussions with executives have identified five challenges for the industry in the region: frugal spending habits, markets with multiple segments, inadequate infrastructure, regulatory complexity, and intense competition (Exhibit 6).

Our survey of MedTech executives reflected these concerns (Exhibit 7). Pricing and reimbursement, talent, and regulatory regimes were all high on the list of challenges.

Exhibit 6

APAC realities for MedTech industry

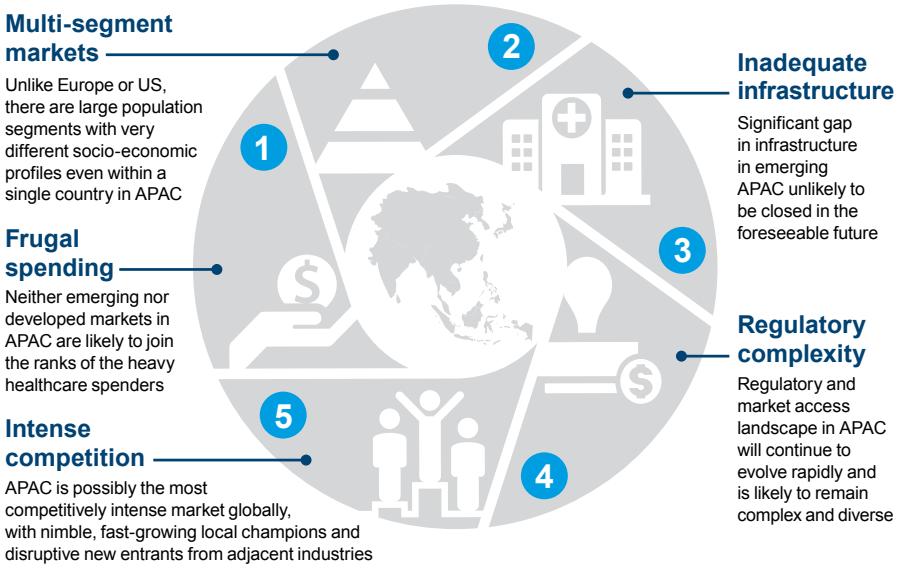
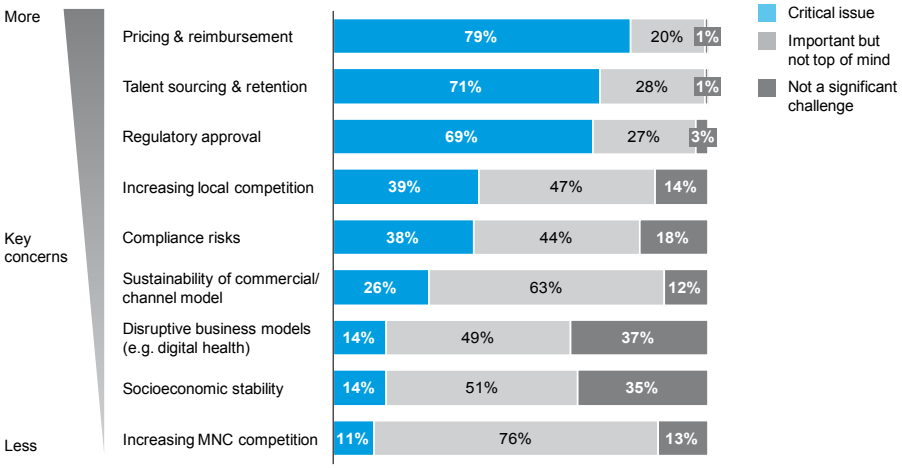


Exhibit 7

Regulatory, market access and talent support are top concerns for executives in the region

How do you rate the severity of the following challenges for your regional/country organization?[1]



1 Figures may not sum to 100%, because of rounding.

SOURCE: McKinsey APACMed Business Sentiment Survey 2015

Frugal spending habits

Consumers and governments in Asia-Pacific are generally more frugal than those in more developed markets. In 2013, annual healthcare expenditure per capita in China was $367, in Indonesia $107, and in India $61. This compared with annual expenditure per capita of $9,145 in the United States and $3,598 in the United Kingdom.

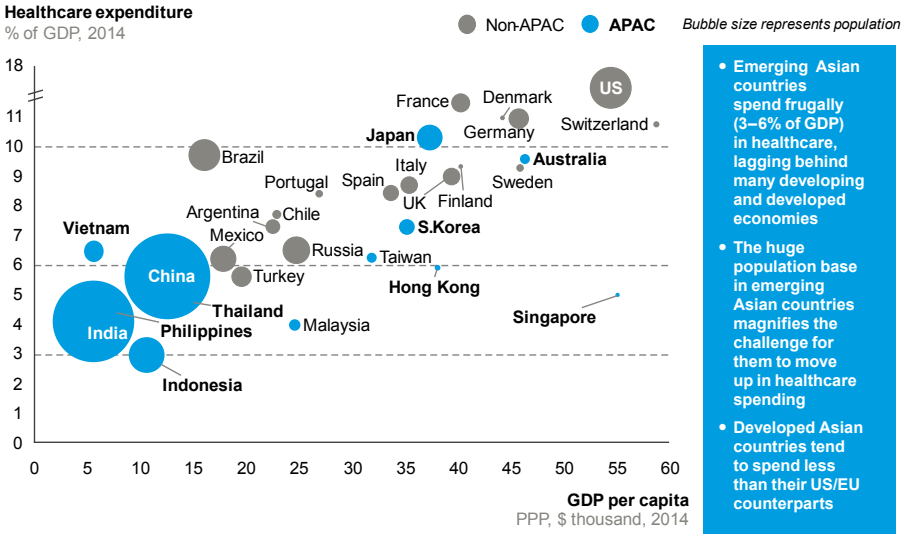
While part of this thriftiness can be tied to lower overall income levels, the share of income spent on healthcare has also been low historically (Exhibit 8). In India for example, GDP per capita in 2014 was less than one-sixth that of the United Kingdom, while healthcare allocations in India, as a share of GDP, were less than half that of the United Kingdom. Even developed countries in Asia tend to spend a smaller share of GDP on healthcare compared with their peers in Europe and North America.

As the region's economies grow, they will certainly spend more on healthcare, but the share of GDP earmarked for healthcare will probably never reach the levels seen in many European markets, let alone in the United States (Exhibit 8). In the more developed Asia-Pacific markets like Australia and Japan, spending on healthcare as a percentage of GDP has stabilized or declined slightly (Exhibit 9). Pressure to keep spending down will continue as governments fight to fund universal healthcare plans, private hospitals become larger and more sophisticated in their procurement practices, and new investors in healthcare provision demand appropriate returns.

Exhibit 8

Most APAC countries are frugal healthcare spenders

Huge disparity of healthcare expenditure between Developed Asia (6–10% GDP) and Emerging Asia (3–6%)

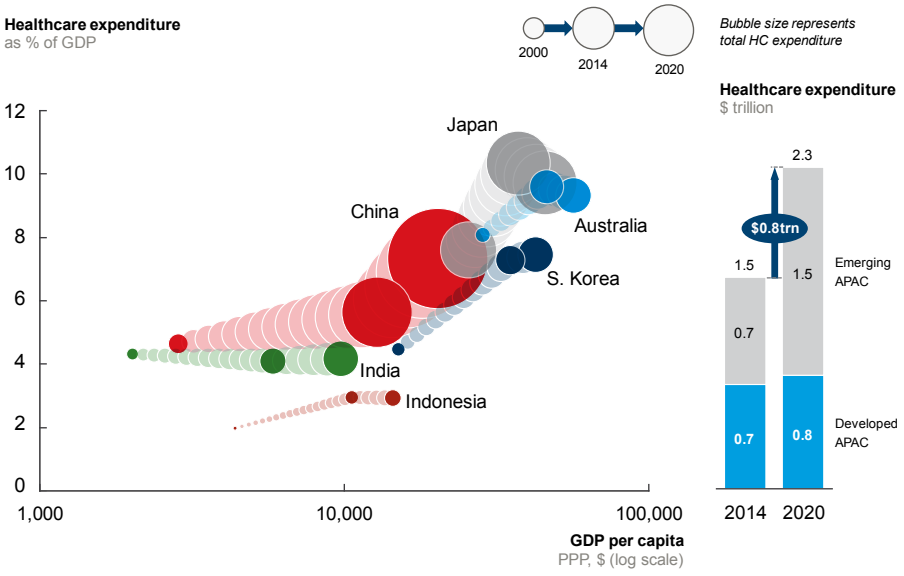


- Emerging Asian countries spend frugally (3–6% of GDP) in healthcare, lagging behind many developing and developed economies
- The huge population base in emerging Asian countries magnifies the challenge for them to move up in healthcare spending
- Developed Asian countries tend to spend less than their US/EU counterparts

SOURCE: IHS Economics (2015); WHO

Exhibit 9

Healthcare spend in the region is growing, driven primarily by rising levels of income



SOURCE: Global insights; IMF; IHS Economics (2015); WHO

Multi-segment markets

The breadth of Asia-Pacific has also created multiple market segments with a wide range of healthcare needs and standards. Even within national markets, disparities in income, culture, disease profiles, and other metrics have led to sub-markets that must be better understood. For example, the market in urbanized East China stands in stark contrast to the one in the more rural and poorer western provinces. These multiple segments also have differing demands for quality and value.

In our survey of industry executives, innovation for the premium and broader segments was named as the highest priority for growth.

Adding to the complexity, MedTech companies have difficulty addressing market segments with very different needs. Many hospitals, and especially the larger urban ones, tend to serve both the premium and broader, more value-focused segments, but most MedTech companies have focused solely on the premium segment. Nevertheless, lower average income levels and general frugality point to a broader segment that seeks better value for money, whether through lower prices, products and services tailored to specific needs, or both. A major challenge for many MedTech companies is how to address this broader segment with market-appropriate products and services through innovation and more-efficient business models while continuing to serve the premium segment.

In our survey of industry executives, innovation for the premium and broader segments was named as the highest priority for growth. These objectives are compatible, rather than conflicting. Companies must find their own balance between the two, while keeping local and global strategies in harmony.

Inadequate infrastructure

Another obstacle to serving the region sufficiently is a relative scarcity of medical personnel and infrastructure. For example, in 2012 there were 12 physicians for every 10,000 people in the Philippines, 7 in India, 4 in Thailand, and 4 in Indonesia (Exhibit 10). All four countries are well below the OECD average of 28 physicians per 10,000 people.

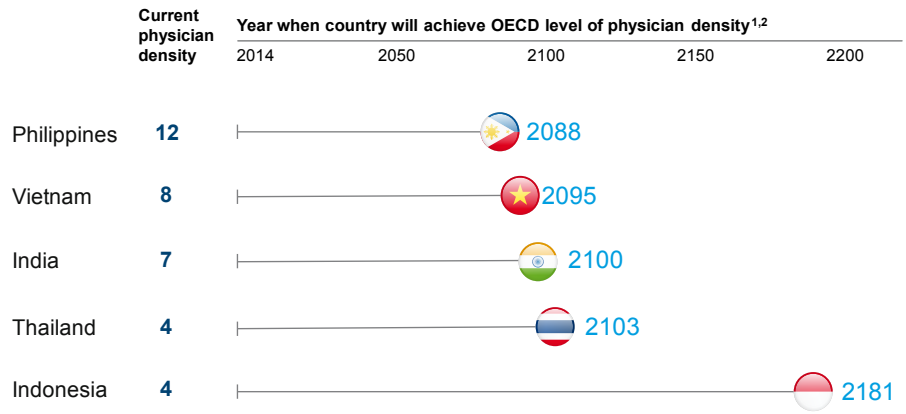
To reach OECD levels, India would have to train an additional 3.1 million doctors. In many Asia-Pacific countries, only a few thousand new physicians are licensed each year and, at the current pace, OECD standards would be out of reach for decades.

Even in one of Asia-Pacific's most developed markets, Japan, the shortage of physicians is troublesome. In 2012, Japan had 23 physicians per 10,000 people. However, these physicians are distributed unevenly, with urban centers like Kyoto boasting about 30 doctors per 10,000 people and other areas, like Saitama prefecture north of Tokyo, half that number. Longer average hospital stays further strain the physician pool in Japan: 17 days compared with an OECD average of 7 days.

Similar shortfalls also exist in other areas relating to infrastructure and the workforce, such as hospital beds, nurses, or diagnostics labs. While growing public and private investment will help expand healthcare capacity and infrastructure in these areas, levels will not match those seen in Europe and North America anytime soon. MedTech companies must adapt their product and service offerings for environments with limited healthcare infrastructure.

Exhibit 10

At the current pace of workforce capacity creation, some APAC countries will not reach developed market levels until the next century



1 OECD average physician density of 28 (weighted by population).

2 Analysis projects the year in which physician density reaches same level as OECD average; assumes number of net new physicians added to the workforce continues at the same pace as average of 2010-15.

SOURCE: Business Monitor International, McKinsey team analysis

For example, training programs must cater to healthcare professionals with less experience and knowledge than those in other regions. They may also have to cover a wider range of professionals, including nurses and technicians, who often play a larger role in healthcare delivery in Asia-Pacific than in other regions.

MedTech companies also struggle with a patchwork of regulatory regimes and reimbursement systems.

Regulatory and reimbursement complexity

MedTech companies also struggle with a patchwork of regulatory regimes and reimbursement systems, each with different capacities, levels of sophistication, and policy priorities. Adding to the burden, the landscape is changing swiftly as governments work to improve access to healthcare.

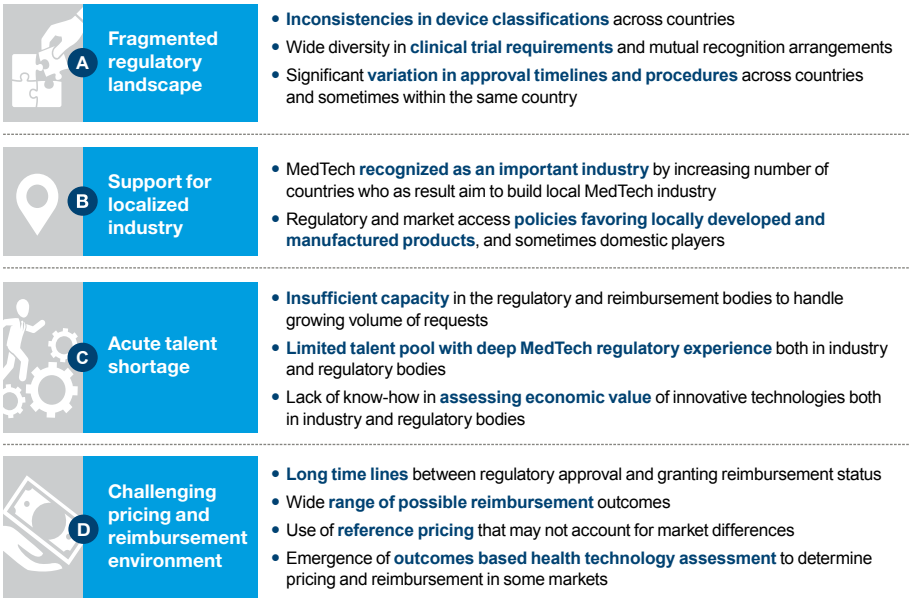
Four characteristics of the regimes in Asia-Pacific are particularly challenging: fragmentation, support of localized industry, capacity, and reimbursement systems (Exhibit 11).

Fragmented regulatory landscape: To some degree, fragmentation of regulatory regimes in the region is unavoidable given the sovereignty of the different countries. However, the nature of fragmentation across and within countries can often involve very fundamental differences that can create additional complexity. As an example, medical devices are classified differently depending on the market, and approval processes can follow disparate timelines and require varying clinical trial requirements. As a result, patient access to medical technology fluctuates from country to country or even within a country.

Support for localized industry: In some markets, global MedTech companies face policies designed to encourage a broader localization of the value chain, especially manufacturing. In China, for example, policies for locally manufactured products and imports can differ significantly in terms of public reimbursement levels and procedures. India is also pushing

Exhibit 11

MedTech industry faces a complex regulatory and reimbursement environment in APAC



public hospitals to buy locally manufactured products. While supporting domestic industry and encouraging global companies to invest locally offers benefits to some stakeholders, such policies can also delay access to innovative medical technology. Requirements for local trials and testing can also add cost and time to bringing new products to patients.

A shortfall in regulatory capacity has been felt in some markets.

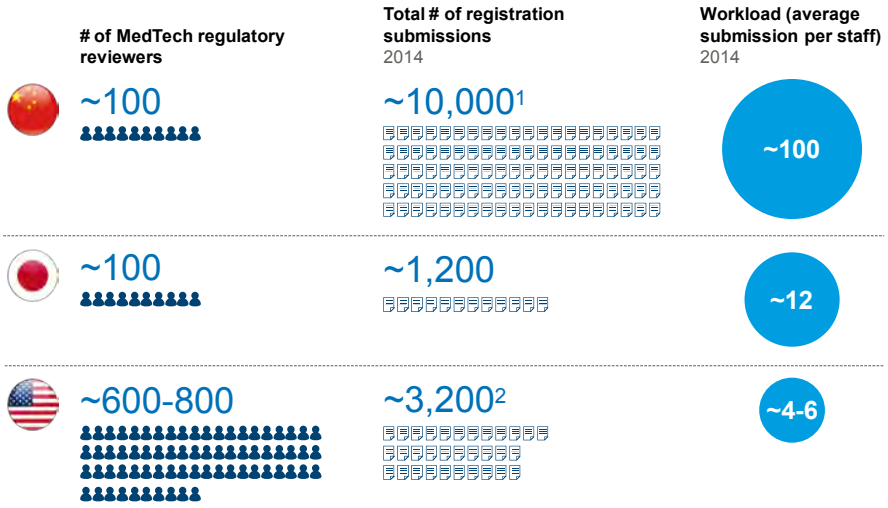
Acute talent shortage: As Asia-Pacific continues to attract multinational and domestic MedTech companies, a shortfall in regulatory capacity has been felt in some markets. This can contribute to longer review times for registrations, variability in the time needed for similar processes, and less time for companies and regulators to discuss and clarify the details around an approval application for an innovative medical technology.

China and Japan also illustrate disparities within the region (Exhibit 12). Each has about 100 regulators who review medical devices, yet in 2014 about 10 times as many registration applications were submitted in China than in Japan. As a result, each regulator in China had to review on average about 100 submissions, compared with about 12 for each Japanese regulator. In contrast, the United States in 2014 had 600 to 800 regulators looking at medical devices, each with an average annual workload of four to six submissions.

Beyond capacity, Asia-Pacific regulators can struggle to stay abreast of rapid advances in medical technology. In many markets, the responsibility for approving medical devices has fallen on agencies that traditionally have overseen the pharmaceutical industry. As a result, review boards and their staff may not have the special capabilities needed to adequately assess clinical trials and other evidence submitted in MedTech applications. The imbalance can be detrimental because medical device reviews require different expertise, and policies drafted from a pharmaceutical perspective can be unnecessarily onerous for MedTech manufacturers, delaying the introduction of new products.

Exhibit 12

Regulatory capacity in APAC is significantly constrained relative to the United States



1 Not including Class II products, which are reviewed by provincial-level regulatory body.
2 Includes 510K and PMA (premarket approval) originals.

SOURCE: Expert interview; FDA; PMDA; press search; CFDA

Challenging pricing and reimbursement environment: The complex range of public and private reimbursement systems, especially for new products, hinders access to medical technology in the region. The challenge will likely become more acute as governments take larger roles in providing healthcare. For example, Indonesia and many other countries have announced plans to provide universal healthcare, which will lead to a larger proportion of medical spending paid by governments that are watching costs carefully.

More countries are also moving toward including outcomes and, eventually, the value created for the healthcare system—a process known as health technology assessments—among the criteria for public reimbursement decisions. These assessments take a multidisciplinary approach to evaluate the effect of medical technology across a range of issues, including their social and economic impact on a health system. While such moves can help control health-system costs, they can also create additional reimbursement hurdles for MedTech companies and may require them to develop new capabilities to satisfy the reimbursement criteria.

Adding to the burden, public reimbursement levels vary widely. Some countries, for example, might offer full reimbursement, while others provide partial reimbursement, with the patient responsible for the remainder. Few regulators in Asia-Pacific maintain end-user price lists, but most track published prices. As a result, reference prices in one country could affect the desired price in another, ignoring market differences that might contribute to any price differential. Further, a company's regulatory processes and decisions in one country can have substantial implications on business throughout the region.

Competition is coming from ambitious new local companies as well as global companies moving in from other sectors.

Some governments are taking steps to address these challenges. In the regulatory sphere, for example, the Association of Southeast Asian Nations (ASEAN) in 2014 signed the Medical Devices Directive aimed at harmonizing the regulatory model across the ten member states and simplifying device registration. Japan has also moved to reduce approval time, in some instances by as much as 20 months. China also recently introduced guidelines designed to speed access to innovative medical devices, including waiving some clinical trial requirements, and the China Food and Drug Administration (CFDA) has taken steps to build more regulatory capacity.

Overall, the regulatory and reimbursement landscape will remain complicated, even if the nature of the complexities changes. Some forward-looking MedTech companies are embracing the shift, although it requires building new capabilities to demonstrate value under health-technology assessments.

Intense competition

In many markets, competition is also adding to pricing pressure. Competition is coming from ambitious new local companies (Exhibit 13) that are often adept at creating market-appropriate products and services, as well as global companies moving in from other sectors, like Google, Samsung, and Tencent.

For example, Mindray Medical International, founded in China in 1991, makes medical monitoring, imaging, and diagnostic equipment, and reported revenues of $1.3 billion in 2014. The company listed on the New York Stock Exchange in 2006 and opened a research-and-development center in the United States in 2012. Many other companies based in Asia-Pacific have also built strong bases in the region and are expanding

Exhibit 13

Local companies have entered major MedTech segments—many have built sustainable businesses

Core business	Listed company	2014 Revenue $ million	Operating margin %	Gross margin %
Stents	Lepu Medical	267	31	63
	MicroPort	355	-11[1]	68
Orthopedic device	Weigao	857	22	59
	Shanghai Kinetic	36	31	62
	PW Medtech	99	35	73
IVD	Kehua Biology	196	27	45
Patient monitoring	Mindray	1,323	15	56
	Edan Instruments	84	-2[2]	54
Medical imaging	Yuyue Medical	271	17	40
	Hokai	149	29	63
Blood pressure/ glucose monitor	Andon Health	69	-20	31
Sterilizer	Shinva	1,015	9	23

1 Increase in operation cost due to acquisition and integration of OrthoRecon.
2 Low operating margin due to 2014 acquisition of Boshibio.

SOURCE: Bloomberg; McKinsey analysis

globally. In China alone, an estimated 15,000 companies are serving the MedTech market. While many may not survive, some could mount a strong challenge to established manufacturers in local and global markets. Digital technologies can help MedTech companies meet the challenges of Asia-Pacific, including cost hurdles, but as they enter the digital realm, they are also encountering competition from established enterprises and start-ups. For example, *The Wall Street Journal* reported that a third of Google's venture capital investment in 2014 went toward health and life science,[1] a huge expansion from previous years. The high-tech giant's interests range from genome mapping to wearable health monitoring devices. Also in 2014, Tencent, a Chinese Internet service portal, invested in an online health information group with plans to offer targeted applications to consumers, doctors, and pharmaceutical companies. In 2015, Tencent launched a blood glucose monitoring unit integrating measurements with a digital platform to track and analyze results.

1 "Google Ventures Shifts Focus to Health Care," *WJS.D*, December 15, 2015, http://blogs.wsj.com/digits/2014/12/15/google-ventures-shifts-focus-to-healthcare/.

Engaging in Asia-Pacific and all its complexity

Playing a bigger role in healthcare in Asia-Pacific requires a new approach. In the past, MedTech companies have tended to import business models that were successful in Europe and North America and were central to building a global business. Instead, companies must understand the unique characteristics of Asia-Pacific and create market-appropriate offerings rooted in innovation that appeal to a broader customer segment.[2]

Senior managers should consider three questions as they decide whether to commit more fully to the region:

- What role does Asia-Pacific play in our global strategy?
- How can we position ourselves in such a diverse market to best serve the region's healthcare needs?

2 Other authors discuss this shift in terms of focusing on the value segment, market-driven offerings, or similar descriptions. We prefer "market-appropriate products rooted in innovation" because it moves the discussion from a focus on price to one encompassing other significant aspects of the strategy, such as innovative products and services that are designed for local markets.

- How do we contribute to shaping the healthcare paradigm in the region, while respecting diversity and varying needs?

The answers to these questions will, of course, be different for each MedTech company. By exploring them, MedTech companies could develop greater insight into the potential rewards for committing to the region, as well as the level of effort needed for success. For most, the potential will outweigh the effort.

Experience and research has shown that MedTech companies engaging more fully in Asia-Pacific should craft strategies around three themes: sustainable business models, market-appropriate products and services, and tailored organizations that address market needs.

These themes are central to opening access to a broad segment of patients, but companies must also recognize that the impact will be gradual. Investments in these areas are a long-term strategy, and any expectations of immediate gains will likely lead to disappointment. In addition, efforts in collaboration with multiple stakeholders, such as physician training and patient awareness, are also crucial to the effort.

Sustainable business models

In many cases, business models that helped MedTech companies enter Asia-Pacific are reaching the end of their life cycles. Senior managers should review legacy models to ensure that they remain appropriate and make changes as necessary. Indeed, our survey suggested executives throughout the region see change as imminent. For example, more than 70 percent of respondents said they believed business model innovation will make a meaningful contribution to their growth in the region.

Although the new models that emerge will be unique in their details, the executive survey highlighted several trends that are likely to dominate. Among the respondents, more than 75 percent said distributor networks in Asia-Pacific will likely consolidate. In this model, larger distributors would focus more on logistics, while manufacturers take the lead in customer relationships.

In addition, more than 75 percent of the respondents said the emergence of multiple channels for sales and customer relations will also lead to new models. Among these, online and mobile sales channels could help redefine customer relationships. Finally, 72 percent of the respondents said direct sales channels will become more important. Key account managers could play a critical role as customers seek a single contact to help them navigate a broad range of offerings.

MedTech companies in Asia-Pacific have typically leaned heavily on extensive distribution networks. Working through distributors helped companies new to these markets gain broader coverage with minimal investment in sales and marketing. Distributors also helped them with customer and regulatory relationships.

But as MedTech companies became more acclimated to these markets, the limits of a business model that relied on distributors became clearer. Perhaps of most concern, the model put one or more layers of intermediaries between the manufacturers and end users. These layers prevented MedTech companies from gaining valuable customer insights,

relinquished most control of customer relationships to the distributors, and allowed manufacturers to be lax in building commercial capabilities for Asia-Pacific.

Although distributor-led models helped keep operational costs low for manufacturers, these tiered systems inflated end-user prices as each layer added costs and extracted its own margin. In part as result, end-user prices for some products are higher in some Asia-Pacific markets than in wealthier Western markets. Tiered distributor networks are also complicated to manage, and the potential for a rogue player can create compliance risks for even the most vigilant organizations.

Beyond these structural disadvantages, manufacturers have found they can capture additional value by providing services and solutions directly to end users, either over traditional channels or more modern digital ones. Such offerings require an intimate knowledge of customer needs, direct negotiations with users, and the ability to put together more complex packages, all of which are made more difficult when working through tiered distributor networks.

Companies will need to reach more hospitals, often in more remote locations, and assemble a complementary, low-cost distribution system.

MedTech companies adopting business models that go beyond the premium customer segment in Asia-Pacific will also have to review their go-to-market approach. Companies will need to reach more hospitals, often in more remote locations, and assemble a complementary, low-cost distribution system. As part of the approach, MedTech companies should also adjust their outreach programs to engage providers and patients who may be less sophisticated or experienced than their usual clientele. Digital channels adapted to local languages and practices could be critical to this effort.

However, MedTech companies must carefully balance the trade-offs of relying less on their distributor networks. By bypassing distributors, they would assume more responsibility for training physicians and other healthcare providers and for supporting a larger range of hospitals more directly. These challenges would add costs, potentially burdening efforts to create market-appropriate offerings for customers outside the premium segment.

New business models should also reflect the differing stakeholder needs created by a more dispersed market, including levels of support, response times, and warranty coverage. Sales incentives and other details of the go-to-market approach would also have to be adapted to the new circumstances.

In addition, MedTech companies will have to develop capabilities to support these changing business models. Among these are:

- **Business Model Innovation:** As a permanent role, this function would take the lead in business expansion, seeking to identify unmet patient needs, coordinating efforts across the organization—including with manufacturing and R&D—and with outside partners to come up with innovative models and solutions.
- **Medical Affairs:** The medical affairs function would focus on discussing the science behind products and services with healthcare providers, leaving the marketing

approaches to others. A rebalancing of commercial and medical functions would follow a pattern large pharmaceutical companies have used successfully.

- **Market Access:** The mandate for this function would be to build stronger capabilities to gain access to the diverse markets of Asia-Pacific. It would take charge, for instance, of navigating the patchwork of decision-making processes, tender requirements, and reimbursement policies in the region.
- **Health Technology Assessment:** By assessing the benefits of medical technology—not only on individual outcomes, but also for health systems as a whole—this function can provide evidence of demonstrable returns. Governments are requesting such assessments more frequently in the course of their pricing and reimbursement decisions.

Market-appropriate products rooted in innovation

Reaching more people in the region will require that global MedTech companies find ways to serve the broader segment of patients who are more focused on value. Many MedTech executives greet this shift and its potential impact on current business with a degree of anxiety, and not all companies will be able to achieve the transition successfully or should even try.

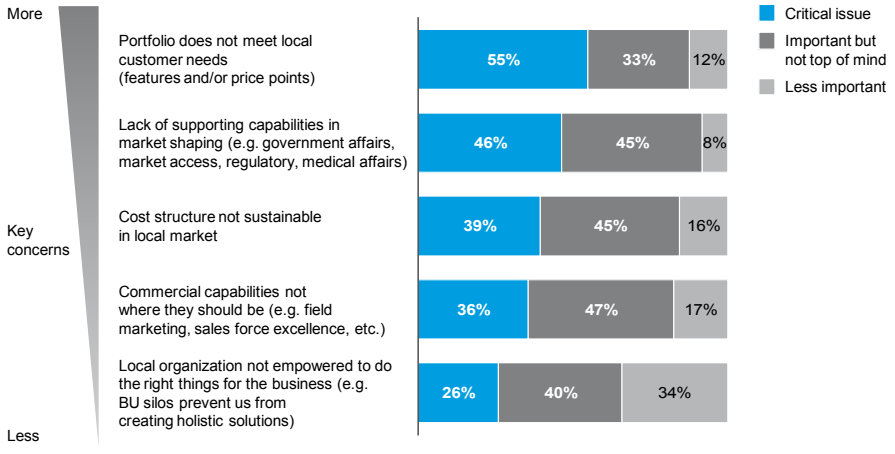
From our executive survey, 55 percent of the respondents cited a portfolio of products and services that doesn't meet local needs as a critical obstacle to growth in coming years, with a further 33 percent saying it would be an important limiting factor (Exhibit 14). In addition, 37 percent said they saw the growth of segments more focused on value as an attractive opportunity, while 44 percent said it was a threat to their business in Asia-Pacific. The split of opinions reflects the complexity of the issue.

In many categories, affordability is critical to serving the broader segment. Across Asia-Pacific the middle class is expanding, but these families, as well as lower-income households, remain value oriented and cannot yet afford premium healthcare. In general, they want quality healthcare, tailored to their situation, at reasonable prices.

Exhibit 14

Locally relevant portfolio and market shaping capabilities are the key limiting factors to growth identified by MedTech executives in APAC

Which of the following issues will be the biggest limiting factors to driving growth for your business in your country/ region?[1]



1 Figures may not sum to 100%, because of rounding.

SOURCE: McKinsey APACMed Business Sentiment Survey 2015

These patients and the providers that serve them want products and services designed with their needs in mind, rather than ones simply imported from foreign markets. For example, software and instructions should be in local languages, and equipment suitable for the smaller body sizes often found in Asia. Local nuances must be understood to successfully serve this segment, which include adapting to differences in disease characteristics, patient flow management, clinical and surgical practices and capabilities, and economics.

So far, few global MedTech manufacturers have committed to adapting their products and services to Asia-Pacific markets.

In some categories, recent global innovation has been incremental rather than groundbreaking, which has led to rapid commoditization. Competition in these categories is putting downward pressure on prices, as well as increasing the expectations of increasingly price-sensitive public health systems. Competing on price alone would put many global MedTech companies at a disadvantage, so instead they must ensure that their overall offerings provide noticeably better value.

So far, few global MedTech manufacturers have committed to adapting their products and services to Asia-Pacific markets. Most focus on offering their global portfolios, sometimes with minimal changes to meet local demands. Exceptions include large equipment manufacturers that have designed radiology and ultrasound products based on local needs, often with the Chinese or Indian markets in mind. Some global MedTech companies are also moving toward designing market-appropriate consumable products, such as intravenous catheters that fit into the workflow and use habits of local nurses and physicians.

One obstacle to adapting products and services to local conditions is inertia. Companies may doubt the need for local adaptation or suspect that doing so would sacrifice quality standards. They may also be unwilling to risk any changes to a business model that has served them well in other markets and seems to be doing fine in Asia-Pacific.

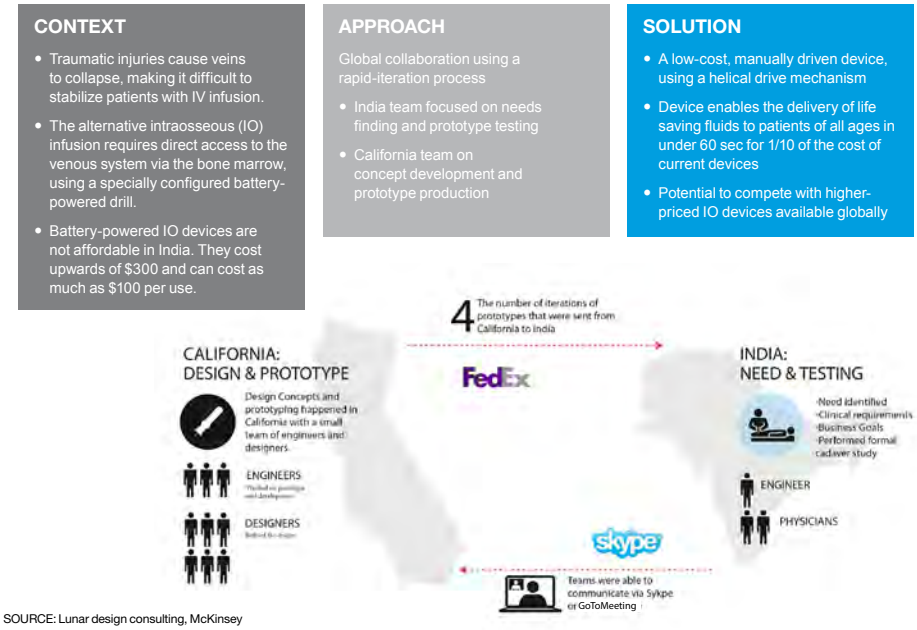
Rather than seeing local adaptation and global offerings as conflicting, companies should take advantage of their global capabilities to create competitive market-appropriate products and services. For example, one MedTech company tackled the issue of supplying market-appropriate bone drills in India by assembling local and Californian teams to find a solution (Exhibit 15). By creating an innovative manual drill mechanism, among other features, the company combined lower cost and high quality. As a result, a much broader range of patients gained access to intraosseus infusions, which can be crucial in treating physical trauma.

Another obstacle is creating offerings for the premium and broader segments that meet internal quality and financial targets. Serving multiple segments adds new challenges in marketing and distribution, and companies must be careful to avoid cannibalization. Any snag in creating a broader offer—for instance, initial margins that are lower than expected, compliance difficulties, or unexpectedly strong competition—could prompt some managers to seek to abandon the effort.

As global MedTech companies explore developing market-appropriate portfolios, two aspects of the transformation are crucial: internal alignment and clear insights into customer needs.

Exhibit 15

Case study: IO BONE DRILL



SOURCE: Lunar design consulting, McKinsey

First, senior executives must agree on the strategic value that a fuller Asia-Pacific engagement presents for their specific market segment and set realistic expectations. A clear definition of the opportunity offered by the market-appropriate products and services means not only delineating the relevant price points, product features, delivery model, and innovation requirements, but also understanding the new customer profiles, their unmet needs, and their geographic distribution.

APAC-led innovation is not only compatible with serving the broader segment; it also is necessary for success.

Once executives clearly define the opportunity, a company must develop a portfolio underpinned by actionable insights into customer needs and behaviors. It would be misguided to take short cuts, such as assuming the broader segment just wants “lite” versions of premium products or discounted last-generation products. Part of the challenge is to create products and services at lower price points, while using innovation to improve standards of healthcare, for example by reducing infections developed during hospital treatment.

The power of adapting offerings to the broader segment comes from combining customer insight with innovation—a concept we call market-appropriate products rooted in innovation. Market insight can also lead to developing specific solutions to disease profiles common in Asia-Pacific, such as a relatively high prevalence of gastric cancers, or different patterns of presentations, such as cancers generally discovered at later stages than in developed markets. APAC-led innovation is not only compatible with serving the broader segment; it also is necessary for success.

Some global MedTech companies have entered the broader market segment through local acquisitions. For example, in 2013 US-based Stryker acquired Trauson Holdings, a Chinese orthopedic implant maker, for $764 million. Mergers and acquisitions can give

global MedTech companies quicker access to the insights and other factors needed for a successful market-appropriate portfolio, including commercial platforms.

If successful, lessons learned and innovations developed for Asia-Pacific can help advance a company's global strategy. Other markets—Africa, Russia, and South America, for instance—also want quality healthcare at lower prices. In addition, health systems in developed markets are seeking to cut costs. Asian MedTech companies are beginning to penetrate these markets, and global companies will be better positioned to defend their market share if their portfolios include value-based offerings.

Tailored organizations

Even as global MedTech companies built businesses addressing the premium segment in Asia-Pacific, most organizations kept substantial control outside the region. Many global MedTech companies have a disproportionately small representation of leaders from Asia-Pacific in senior management and board levels (Exhibit 16).

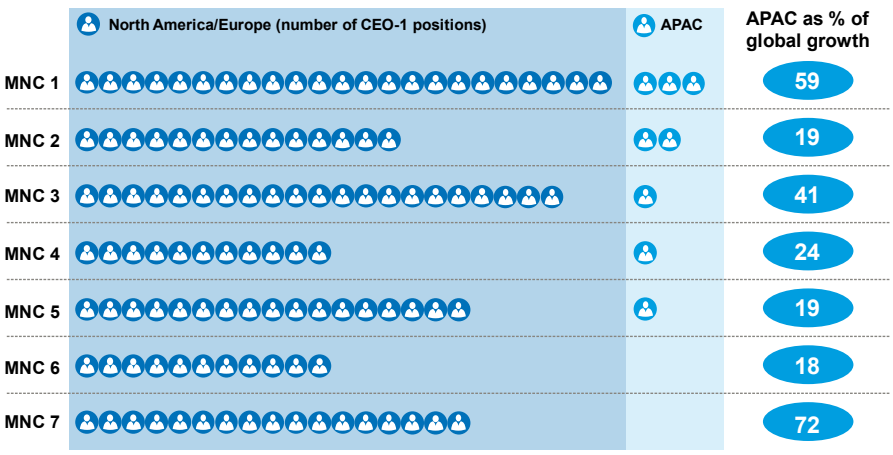
While regional leaders oversee operations for most companies, major decisions generally require approval from managers outside the region, most of whom were educated and built their careers largely in Europe and North America. MedTech companies should strive to find a better balance between local autonomy and corporate checks and balances.

At times, global organizational structures designed to create broad, immediate efficiencies are not flexible enough to support initiatives in Asia-Pacific that may offer benefits over a longer period. For example, decisions on whether to add manufacturing capacity often fall to a global operations chief outside the region, who might see cost advantages to adding factory lines to existing plants in Europe or North America rather than opening a plant in Asia-Pacific. Someone more aware of Asia-Pacific's potential could understand the longer-term benefits of building capacity in the region immediately and preparing for market growth.

Exhibit 16

APAC has significant headroom to grow its leadership representation in global MedTech

Using geographic location[1] as a proxy, we find that there is very limited "voice of Asia" representation among top executives at major MedTech MNCs



1 Primary working locations as of August 2015.

SOURCE: Company websites; LinkedIn; McKinsey team analysis

Corporate organizations need to evolve to assure that regional experts have an appropriate voice in such decisions.

Organizational models designed to extract the greatest value from Asia-Pacific should revolve around four concepts: empowering market experts at all levels, establishing regional facilities, building capabilities, and creating trusted internal relationships.

The ideal organization would strike a balance between taking advantage of global assets and capabilities and giving Asia-Pacific managers enough autonomy to react to local market developments.

Empowering market experts: Even a cursory review of the organizations of global MedTech companies shows that boards of directors and executive suites are dominated by leaders with little or no experience in Asia-Pacific. Without peers who grew up, studied, and built careers in Asia-Pacific, senior leaders find it more difficult to understand the factors that underpin performance in the region or to craft a winning strategy.

Also, as Asia-Pacific contributes a greater share of global revenue and profits, such high-level expertise would add to a company's competitive advantage. MedTech companies should actively seek qualified candidates from the region for their boards and senior executive teams.

In addition, companies should consider moving appropriate business units to Asia-Pacific, in particular those that expect a growing share of revenues to come from the region. Some industry leaders have already taken such steps. For example, Philips moved the headquarters of its mobile surgery business unit to India and GE Healthcare relocated its X-ray business unit to China. Such relocations should include moving centers of excellence nearer to the relevant markets. When motivated by strategic priorities, organizational shifts like these allow companies to take advantage of local expertise at all levels, from early-tenure market researchers to senior business unit leaders.

The ideal organization would strike a balance between taking advantage of global assets and capabilities and giving Asia-Pacific managers enough autonomy to react to local market developments. For example, local leaders should be able to reallocate resources quickly to respond to growth opportunities, tailor value propositions of the product portfolio, and adjust commercial models.

Establishing regional facilities: MedTech companies should evolve from importing products and innovative technology into Asia-Pacific to establishing a solid R&D and manufacturing presence there. Opening R&D centers and manufacturing plants can deliver a range of benefits, from capturing insights from staff with intimate knowledge of the region to being nearer customers, suppliers, and other stakeholders.

Exhibit 17

Leading MedTech companies have invested significantly in APAC

Contribution to APAC by 11 leading MedTech companies, based on McKinsey APACMed benchmarking survey

R&D footprint

28 Number of R&D facilities in APAC

2,300 Total staff involved in R&D

Manufacturing footprint

48 Number of manufacturing facilities in APAC

28K Number of employees employed in manufacturing plants in APAC

SOURCE: McKinsey APACMed data benchmark 2015

Many global MedTech companies have already established R&D and manufacturing centers in Asia-Pacific, often representing substantial investments (Exhibit 17). Together, the 11 global MedTech companies examined in detail had created 28 R&D centers in Asia-Pacific by 2015 and employed 2,300 people there.

Building more R&D centers in Asia-Pacific also would allow companies to tap into talent flowing from some of the world's best universities.

Local R&D centers can capitalize on staff with a clearer understanding of Asia-Pacific market needs and behaviors, collaborate with local institutions and start-ups, establish closer relationships with regulators, and develop and test prototypes more quickly. Rather than mirror R&D centers at headquarters or elsewhere, they should be allowed to create a global center of excellence in their own image.

Building more R&D centers in Asia-Pacific also would allow companies to tap into talent flowing from some of the world's best universities. In 2015, China's Tsinghua University placed first in the *U.S. News and World Report's* ranking of global engineering schools. Altogether, Asian schools accounted for six of the top ten engineering universities in the US publication's annual list.

Regional manufacturing plants also benefit from easier access to local supply chains, including access to quality components for lower prices. In addition, local content can be beneficial when competing for public contracts. Together, local R&D and manufacturing facilities can also accelerate time to market for new products and services.

For greatest success, local facilities must be treated as peers with their counterparts in other locations. Over time, Asia-Pacific centers should have the authority to make more independent decisions on key priorities for the region, while staying coordinated with global headquarters and leveraging global capabilities. If they are constantly required to seek approvals from headquarters, time to market is lost and frustrations may develop. In addition, the perceived absence of autonomy may affect recruitment and talent retention.

Building capabilities: MedTech companies should also invest in building capabilities to create strong, self-supporting organizations. Training programs should cover the same range of skills needed elsewhere and in particular include a leadership development component, a key gap often observed in Asia-based organizations. Some capabilities, however, are particularly relevant to Asia-Pacific. For example, to adapt to the broader market segment, training in design-to-value topics or approaches to gaining customer insight could be especially important.

These programs should be crafted to strengthen capabilities, skills, and a common set of corporate values without sacrificing individual creativity and problem-solving approaches. Groupthink is not the goal. Establishing Asia-Pacific training centers and corporate academies should be part of the effort to develop capabilities.

Creating trusted relationships: Throughout an organization, developing an atmosphere of collaboration and trust between Asia-Pacific staff and their counterparts elsewhere is crucial. Cultural obstacles, such as different approaches to handling confrontation, language differences, and unconscious biases can get in the way of forming collaborative relationships among colleagues separated by geography. Companies must work to overcome these issues.

Common measures for bridging such divides include job rotations into and out of the region for talented professionals and site visits to Asia-Pacific facilities by corporate leaders and functional experts. Incentives and key performance indicators that reward collaboration and cascade through all management levels can help ensure that the intentions of senior management are put into action.

Collaborating for better outcomes

While MedTech companies can do more to bring their products and services to a broader range of patients in Asia-Pacific, tighter collaboration among stakeholders in the region's healthcare systems—governments, providers, patients, educators, companies, and industry associations—is fundamentally needed to address common issues and improve healthcare delivery for patients.

Our survey of Asia-Pacific MedTech executives showed that an overwhelming 81 percent of respondents felt regulatory advocacy was a major issue for the industry, followed by 62 percent who saw physician education as an important area for industry action, and 54 percent who chose development of the talent pool (Exhibit 18).[3]

Regulatory regimes

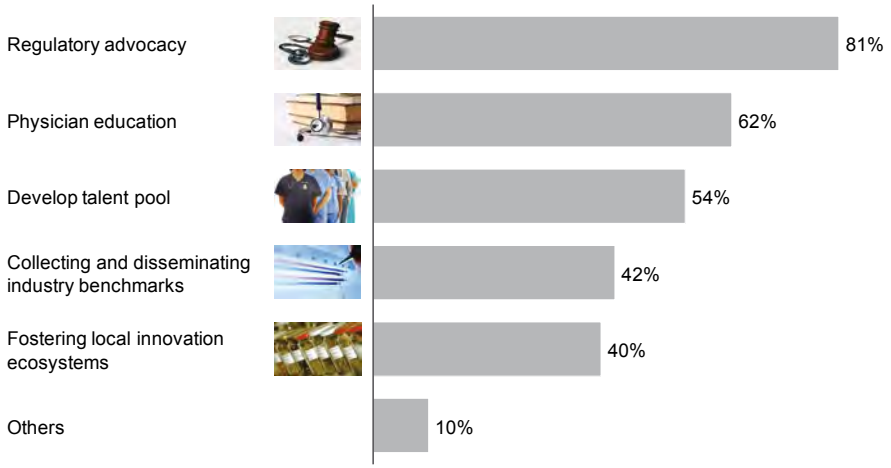
By a wide margin, Asia-Pacific MedTech executives saw improvements to regulatory regimes as the most important issue facing the industry. Asia-Pacific regulatory systems are

3 Multiple responses were allowed.

Exhibit 18

MedTech executives in the region believe regulatory advocacy and physician education are key opportunities for industry-wide collaboration

What do you think are the key opportunities for industry-wide collaboration?
# of respondents, n=124



SOURCE: McKinsey APACMed Business Sentiment Survey 2015

unlikely to coalesce around a unified policy toward healthcare, but common ground can be found to help ease the burden on companies bringing products and services into the region. Efforts can be based broadly, such as the ASEAN Medical Devices Directive, or confined to a single market, but the ultimate goal is to improve access to the best care.

Executives said regulatory hurdles have been a significant factor in delaying the introduction of medical technology to the region (Exhibit 19). For example, one study looked at innovative technologies cleared by the US Food and Drug Administration (FDA) between 2010 and 2014 and found that only 38 percent of them had been approved and brought into China by mid-2015. Although business considerations such as customer affordability were undoubtedly factors, regulatory hurdles and import restrictions were also crucial obstacles.

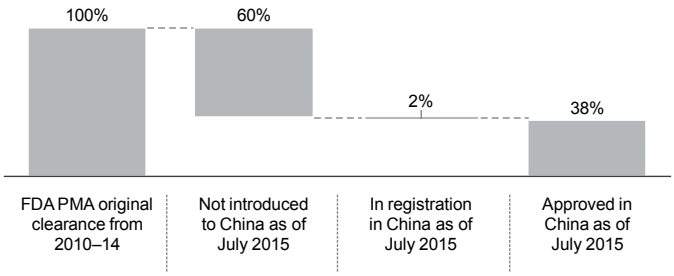
Other markets have successfully streamlined the approval processes for health industries without compromising safety or quality, and Asia regulators could draw from their experience. For example, in the United States, the Prescription Drug User Fee Act, passed in 1992, played an important role in speeding the introduction of pharmaceuticals (Exhibit 20). The legislation, a reaction to dissatisfaction with approval delays and regulator capacity, allows the FDA to collect fees from the industry to fund improvements in the approval processes. As a result, between 1993 and 2001 the number of full-time application reviewers nearly doubled and approval time for non-priority drugs was halved in some cases.

Regulating medical technology is a relatively new mandate for most governments in the region and recruiting regulators with appropriate skills has been challenging. In many countries, regulators reviewing submissions for medical devices have backgrounds in other disciplines and no formal training in MedTech fields. One of the region's leaders, Singapore, only created a branch of its Health Sciences Authority dedicated to medical devices in 2007, with full implementation of regulations starting in 2012.

Exhibit 19

The late introduction of innovative products to APAC is a combined outcome of company business decisions and local regulatory hurdles

Status of products from US to China
% of products



Potential reasons for delayed introduction of innovative products to APAC:

- Diluted business value due to different regulatory requirement between FDA and APAC
- Products not developed for local needs
- Afforability contraints
- Lack of skilled workers to operate in APAC
- Import restrictions

SOURCE: CFDA ; GBI

Singapore also offers an example of how to approach the shortage of qualified healthcare regulators. In 2014, the country established the Centre for Regulatory Excellence (CoRE) as part of the Duke-NUS Graduate Medical School.[4] The center's mission, according to its website, is to "enhance collaboration and promote thought leadership in innovative regulatory science and policy within national regulatory agencies, industry, and academia." In a separate program, the National University of Singapore, in collaboration with the Regulatory Affairs Professionals Society, offers a graduate certificate in medical devices regulatory affairs based on online and in-person instruction.

Governments throughout Asia-Pacific could use existing programs or set up similar centers of their own to accelerate the growth of regulatory capabilities. These institutions could develop and deliver academic programs designed to produce professional regulators for healthcare systems, working closely with regulatory agencies and industries. Companies could support the effort through scholarships and sponsorships and by providing global experts on specific topics for seminars and other programs. Agencies, in turn, could commit to use such centers for staff training.

Academic institutions and trade associations could also help provide a knowledge base shared by regulators and industry leaders to create a common understanding of healthcare objectives and policy tools. They can also help foster mutual trust and respect among regulators and industry practitioners. Finally, they could be incubators for innovative regulatory approaches suitable to Asia-Pacific. As a byproduct, these institutions would enhance the talent pool for regulatory affairs positions within the industry.

4 The Duke-NUS Graduate Medical School is a collaborative program between Duke University in the United States and the National University of Singapore, supported by Singapore's Economic Development Board, Ministry of Health, and the Health Sciences Authority.

Exhibit 20

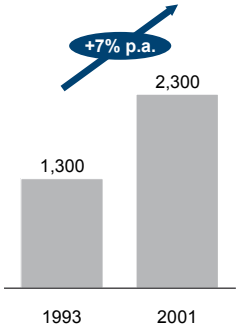
Case study: PDUFA has played a significant role in reducing approval time for US drug registration

Overview

- **PDUFA** was launched **in 1992**
- This initiative was launched in order to fund the US drug approval process
- Companies pay fees according to the guideline
  - **Application fees**: Fees occur when an application is submitted
  - **Establishment fees**: Annual fees for each company
  - **Product fees**: Annual fees for each product
- Fees are used to enhance effectiveness of the drug approval process

Initiatives taken

Number of full-time reviewers at FDA
People



Impact

–13

Median time for non-priority drugs **dropped by 13 months** from 27 to 14 months (1993-2001)

9/10

During 2000–2010, goal to review products in **6 months**[1] achieved **9 out of 10 years**

1 Goal for priority submissions.

SOURCE: Government Accountability Office

Appropriate collaboration between regulators and industry is vital to improve access to medical technology, while safeguarding the welfare of patients. While stakeholders understand the benefits of working together, relationships that are perceived as too close can fuel concerns that policies favor corporations. Neutral institutions, such as academic programs, could provide platforms from which to address common issues.

While nurses, radiologists, and other specialists are also needed, the shortage of physicians is a critical bottleneck.

Healthcare talent

Stakeholders can pool resources and ideas to address the regional shortage of healthcare professionals, particularly physicians. While nurses, radiologists, and other specialists are also needed, the shortage of physicians is a critical bottleneck to accessing medical devices since doctors are the final link to patients. In our survey of MedTech executives, 93 percent said a shortage of trained healthcare professionals prevents patient access to better healthcare and industry growth.

The shortage of qualified physicians stems from a number of factors, many of which will require years to address:

- **Institutional capacity:** Asia-Pacific lacks qualified medical schools to train the number of physicians it needs. In Indonesia, for example, enrollment in medical schools is full, yet the country produces just 6,000 to 7,000 doctors a year. Indonesia has about four physicians per 10,000 people, and at the current training rate it would need more than a century to match the OECD average of 28 doctors per 10,000 people. Even in countries building medical schools, a shortage of qualified instructors could remain a bottleneck.

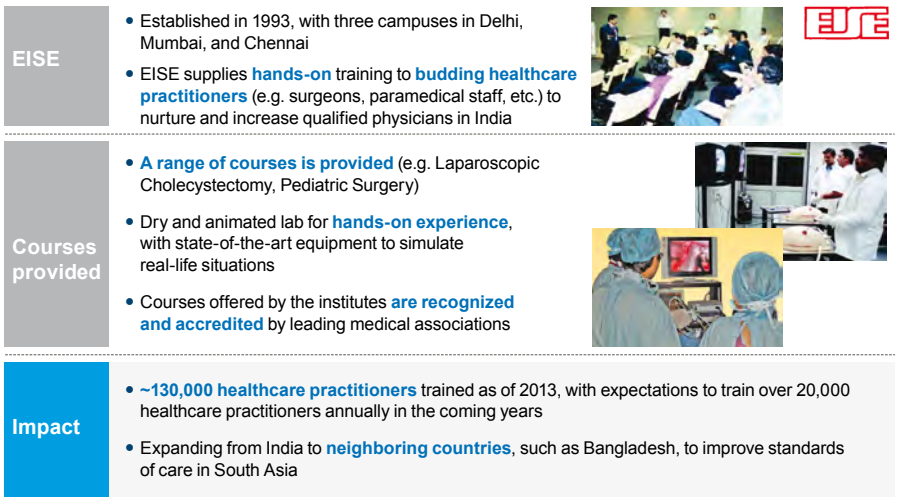
- **Training duration:** Training in some specialties in Asia-Pacific, such as cardiothoracic surgery, can require up to a decade of undergraduate and medical school. Although this is only slightly longer than international averages, the time needed for a medical degree presents a bottleneck, limits capacity at medical schools, and can be a disincentive for some prospective students.
- **Diverse quality:** Despite a general commitment to quality education, standards at medical schools across Asia-Pacific vary significantly. Many schools do not have the resources to buy the equipment needed to teach the latest technologies or, in some cases, even a sufficient number of cadavers for traditional instruction.
- **Tuition costs:** In some countries, a medical degree can be prohibitively expensive. In India, for example, medical graduates from private schools need 10 to 20 years to earn back the cost of their degrees. While this is not very different from more developed markets, there are usually fewer sources of education financing and the upfront investment may be too steep for families with insufficient means. As a result, many of the most talented students may choose different careers. The problem is especially onerous in specialties like surgery that require additional years of training.

Global MedTech companies are already active in medical training in Asia-Pacific. Our study showed that 11 major companies together invested about $130 million in 2014 to train about 250,000 healthcare professionals, including physicians, nurses, radiologists, and diagnosticians. For example, the Ethicon Institute of Surgical Education (EISE), run by Johnson & Johnson Medical, has three campuses in India and offers a range of courses on topics from laparoscopic cholecystectomies to pediatric surgery (Exhibit 21). Other MedTech companies, such as Medtronic and Abbott, also operate similar centers in Asia-Pacific.

A collaborative effort to address the region's physician shortage could also help. Accreditors, academics, regulators, and business leaders could work together to find ways to shorten the length of medical school programs, allowing doctors to graduate faster and freeing capacity at institutions.

Exhibit 21

Case study: Leading MedTech companies have invested significantly in building educational facilities to provide basic and advanced training



SOURCE: Ethicon Institute of Surgical Education (EISE); literature search

While practical experience remains essential, modern technologies could be used to streamline programs generally without lowering quality.

While practical experience remains essential, modern technologies could be used to streamline programs generally without lowering quality. Companies such as Japan's FASOTEC have engineered 3D-printed organs that feel, respond, and even bleed realistically to help improve surgical skills (Exhibit 22). The prices—for example, $130 for a bladder—make them a reasonable substitute for actual organs in medical training, and prices are likely to fall with increased production.

Other global initiatives are also using advanced technology to create virtual experiences that can accelerate medical education (Exhibit 23). A collaborative effort by Microsoft and Case Western Reserve University, HoloLens offers an augmented-reality system that uses special glasses and high-definition 3D graphics to teach anatomy and other subjects. The National University of Singapore is exploring programs that simulate medical settings—such as emergency and operating rooms—in extreme situations, much like flight simulators are used in training pilots. These innovations allow medical students to practice procedures frequently while receiving instantaneous, personalized feedback.

Since some of these new technologies don't have established track records, university medical schools may be reluctant to commit limited funds without additional evidence. Companies could encourage the shift by sponsoring pilot programs to demonstrate the effectiveness of these new teaching tools. The trials would attempt to document whether students reach similar levels of proficiency faster than traditional methods and can safely transfer these skills to clinical environments. Such pilots would also be a step toward learning how to integrate the tools into university curricula and adapt them to local circumstances.

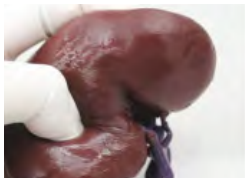
Exhibit 22

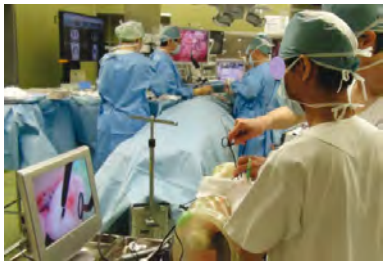
Case study: Cutting-edge technology transforming medical education

Artificial organs engineered by 3D printing enable ultra-realistic training to improve physicians' surgical skills

- FASOTEC, a Japanese company, engineers **3D printed organs** e.g. hearts, brains, and livers
- Printed organs have realistic "biotexture" — they squish and bleed like the real organ
- Printed organs are used for **surgical training and practices** to improve physicians' surgical skills
- These organs are produced at a **reasonable cost** – e.g. $130 for 3D-printed bladder

FASOTEC





"Not only young, inexperienced doctors but also experienced doctors can perform a better operation if they can have a rehearsal first on these 3D-printed organs."

–Surgeon in Kobe University Graduate School of medicine

SOURCE: Company website; press release

Exhibit 23

Case study: Cutting-edge technology transforming medical education

Current state

- Traditional medical education still heavily reliant on using **cadavers and anatomical models** to teach human anatomy
- Cadavers are **expensive and difficult to source**, making them difficult to access regularly
- Besides cadavers and models, most medical education still based on **two-dimensional medical illustrations**

Emerging disruptors

- **Microsoft HoloLens** exposes students to virtual, 3D holograms of the human anatomy to see how bones, muscles, and organs work together in the human body without resorting to cadavers
- Similar technologies are currently in development in **APAC**—for e.g. Singapore's NUS is developing a **3D simulation platform** for lifelike scenarios like a mass-casualty incident, a hospital ER, or an operating theater
- Some of these technologies have already been tested, with excellent feedback from teachers and students

"The mixed reality of the HoloLens has the potential to revolutionize [medical] education by bringing 3D content into the real world."

– Head of research, Medical Educator

"I had a moment where I found the aortic valve and it was actually the first time i'd seen the valve in relation to all the other anatomical structures. It was a way of seeing it that you couldn't do with an actual heart."

– Medical Student

SOURCE: Company website; press search

Using technology to speed the training of medical professionals requires more than pilot programs; a range of stakeholders must buy in. Educators would have to be willing to modernize their programs and acquire the skills needed to use the new tools. Governments would have to be ready to fund the upgraded programs, and accreditation bodies would need to revise models used to evaluate medical school programs.

In tandem with initiatives to improve the training of healthcare providers, regulators, academics, and corporations must also enhance their patient engagement. Educational outreach programs and medical referral systems are among the collaborative measures that can encourage patients to seek healthcare more actively.

Delivery paradigm

Collaboration among a range of stakeholders can also help orchestrate a more fundamental change in healthcare delivery. New ideas and technologies are available to create more efficient and cost-effective systems and improved outcomes, but entrenched behaviors and beliefs, as well as traditional frameworks for healthcare funding and reimbursement, often block access to these benefits.

In many Asia-Pacific markets, healthcare is organized around hospitals, even though they are widely recognized as a resource-intensive way to provide care. And cost is not the only issue. In many instances hospital-based healthcare has fallen short of its general mission to make high-quality care available to the patients they serve. For example, China has invested heavily in a tiered hospital system, aiming to bring hospitals and clinics within reach of even remote rural residents. However, rural clinics and healthcare centers remained underused years after opening, while major urban hospitals are overcrowded as patients flock to what they perceive as a higher level of care, even for minor ailments.

Asia-Pacific isn't the only region facing these challenges, but it is uniquely placed to discover solutions.

Medical technology can help challenge the status quo. It can help shift healthcare delivery to less costly settings and ultimately to patients' homes, as appropriate, and increase the overall capacity and effectiveness of healthcare systems. Home monitoring systems, for instance, can relieve hospital bed shortages. Applications such as diabetes monitoring systems for smartphones and other handheld devices can improve treatment regimes and outcomes as patients become better managers of their own disease, requiring a lower level of immediate support from healthcare professionals. Sharing patient information across institutions digitally can lead to better diagnoses and treatment programs. All contribute to system efficiencies, increasing access to available resources, but also require a general acceptance to new approaches to offering healthcare.

Healthcare professionals generally acknowledge that changes are needed in healthcare delivery systems and, as pilot projects in many regions have demonstrated, advanced technology has made alternative models feasible. Yet, change has been slow in Asia-Pacific. Two reasons standout. First, the shift requires a range of expertise that is difficult to assemble, including disease-specific knowledge, technology, behavioral change management, data analytics, and visualization. But, just as important, it requires a coordinated effort by stakeholders, particularly providers and payors, as well as the industry, to design solutions that contribute to sustainable changes in healthcare delivery.

Asia-Pacific isn't the only region facing these challenges, but it is uniquely placed to discover solutions. Healthcare systems there are under pressure on many fronts, providing the will to act. Moreover, the region isn't as burdened with legacy approaches as are more-developed markets, offering an environment more amenable to innovation. Finally, many industries, from high tech to pharmaceuticals, are also focusing on the region, creating a critical mass of creative thinking and the potential for cross-industry collaboration.

Areas where the Asia-Pacific region can take a lead in developing much-needed solutions for healthcare delivery include:

- **Elderly care:** Pilot projects could create communities that demonstrate the benefits of "aging in place," assisted living at an individual's home enabled by technology. Medical support using mobile applications and other value-added services could be tested in real-world settings.
- **Acute care:** Hospital-at-home programs, where acute and post-acute patients recover at home, are possible using remote support systems and healthcare providers with lower skills than those at acute care hospitals.
- **Chronic diseases:** New technology has enabled improved prevention and management of chronic diseases, including diabetes, hypertension, and related cardiovascular comorbidities.

Exhibit 24

Case Study: B. Braun offers solution for chronic kidney disease treatment in India via partnership with state government

Limited access to treatment for chronic kidney disease

- **200 per million** — Estimated incidence rate of end-stage renal disease
- **40%** — Deficiency in availability of dialysis machines in Andhra Pradesh
- **INR 10,400** — Monthly cost of dialysis treatment versus average income of INR 7,400
- **Up to 200 KM** — Distance traveled to access dialysis treatment

B. Braun launched a partnership with the Andhra Pradesh state government for hemodialysis

Key features of program:

- **Cashless treatment:** Patients below poverty line covered by state government insurance scheme
- **Easier access:** PPP established 18 centers with 254 state-of-the-art dialysis machines
- **High-quality care:** Medical and operational staff trained by B. Braun; nephrologists sourced from the government hospitals
- **High safety levels:** Infection control protocols in line with international guidelines
- **Enhanced utilization:** High utilization of machines through higher patient volumes (26 days/month, 18 hrs/day)
- **Digital care management:** Technology platform for granular tracking of clinical outcomes, quality, and financial metrics
- **Local adaptation:** Reuse of dialyzers; usage of selected locally manufactured products

Outcomes

- Over **250,000** dialysis treatments performed in 2014
- Cost per treatment is approximately **1/10th** of developed countries
- Supply deficiency reduced from **40 to 28 percent**

SOURCE: B. Braun homepage; expert interview; press search

Public-private partnerships have been successful in other industries, and could be useful in bringing accessible medical technology to a broader range of patients in Asia-Pacific. In one early example, the German MedTech company B. Braun has worked with the government in the Andhra Pradesh state in southeastern India to provide greater access to dialysis for low-income patients (Exhibit 24). The company has invested about $3.3 million in the project and has opened access, in part, by installing more dialysis machines, increasing utilization, and finding a better balance between physicians and other medical staff in its operations. Despite such early efforts, a clear model for sustainable and scalable public-private partnerships in medical technology has yet to emerge for many of the regions' most pressing healthcare challenges.

By working together, public and private leaders could identify the most promising models and expand their use, improving access and outcomes for patients. Successes in these areas could be applied elsewhere around the globe.

Conclusion

In just five years, Asia-Pacific will likely be the world's second-largest market for medical technology, home to two of the top three global markets, with several other large ones climbing the ranks. Continued hesitancy to embrace the region by major companies risks losing Asia-Pacific to domestic start-ups and global giants from adjacent industries, while also denying access to a broad segment of patients the full range of advanced medical products.

Although the region presents challenges, companies serious about engaging more fully there can take several steps to move ahead. Business models that provide a greater understanding of the region's healthcare needs, market-appropriate products and services rooted in innovation that appeal to a broad segment of patients and providers seeking greater value, and more Asia-Pacific managerial expertise are all within reach of companies setting out to expand in the region.

Collaborative efforts among stakeholders—regulators, academics, healthcare providers, companies, and trade groups—are also needed to lower barriers to improved access for

Asia-Pacific patients. Based on our experience and interviews with MedTech executives, areas needing immediate attention include regulatory capacity and capability, inadequate infrastructure, especially a shortage of doctors, and a general reluctance to accept new ways to offer healthcare.

There's no doubt that most global MedTech companies can overcome these challenges. If they succeed, they will help bring modern medical technology to more, underserved patients throughout Asia-Pacific. At the same time, they will be developing innovative products and services that can benefit patients worldwide.

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