



# The changing landscape of the medical devices industry in the APAC region



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# 1. Introduction - the APAC region



# 1.1

## APAC and its massive healthcare potential

Medical device companies across the globe are contemplating to enter the Asia-Pacific (APAC) market to expand their business. This thought leadership illuminates the massive potential that APAC holds and how the medical device market is increasingly focusing on strengthening their regulations along with building a unique distribution network across the countries.

APAC is home to seven of the world's 10 most populous countries and over 60 percent of the global population. The region is characterized by a diverse population with a wide range of cultural, demographic and economic backgrounds. The sheer magnitude of the population, coupled with strong economic indicators, means that the healthcare market in the region is forecast to grow tremendously in the future. If forecasts hold true, the region will soon outpace the US and Europe when it comes to driving healthcare demand.

Within this growing demand for healthcare services, medical devices play a key role in the overall segment. APAC is experiencing strong growth in demand for medical devices, forecast to grow at 7.0 percent from 2018 to 2022<sup>1</sup>, surpassing Europe to becoming the second largest market globally. With rising income levels, swelling private sector investment and government incentives in the medical devices space, the market is poised for strong growth in the coming years.

Furthermore, the region is a prime location for manufacturing and sourcing for global medical companies. The growth is further accentuated by rapid technological advancements and recognition that these products create value for patients and value-focused healthcare systems. Market players, both domestic and international, are growing their investments towards innovation in the industry.

In order to meet the demand of this heavily populated market, companies are expected to step out of their conventional roles.

Quality and affordability need to go hand-in-hand, as medical device companies seek to play a larger role in the value chain and further connect with customers and patients.<sup>2</sup>

A key enabler in meeting the growing demands of the region is the focus on establishing a comprehensive and efficient distribution network. Each player of the value chain plays an integral part in ensuring the seamless functioning of the system from a regulatory and market stand-point. The role of distributors and third-party players is growing considering the expertise they bring to the market, especially for international companies planning to enter the region.

In order to get a holistic idea of the market, it is important to analyze countries ranging across the spectrum. This would include mature markets of Japan and Australia, countries with growing population such as China and India, and emerging markets including Malaysia and Thailand.

Understanding the nuances of each country's value chain and regulations might seem daunting, however, is extremely crucial for any international company to understand, particularly those aiming to establish a network in APAC. It is imperative for these global players to keep an eye on APAC for the massive opportunities and talent it holds; be it from the perspective of growing demand or as the hub of innovation that the region is gradually becoming.



1. "Worldwide medical device market forecast", Fitch Solutions report  
2. "Improving access to high quality healthcare across Asia Pacific", APACMed, [Link](#)

## 2. Country overview



# 2.1 Macroeconomic indicators fueling growth of APAC's medical devices market

By 2023, while China and Japan are estimated to continue to lead Asia-Pacific in terms of GDP (current prices), the other markets in the region will see a significant uplift in real GDP growth to outpace the larger markets. This growth trend will be led by India and followed Thailand and Malaysia.

## The global economy is slowing but APAC continues to record strong growth

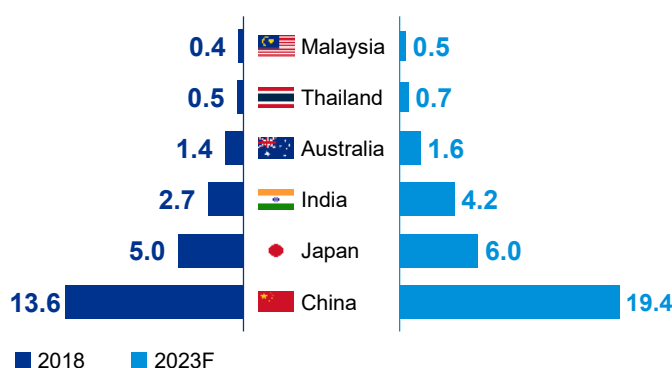
Despite the global economy slowing, owing largely to ongoing trade disputes, APAC has continued to record robust economic growth rates. Reflected as the world's principal growth engine, the region accounted for over 62 percent of the global GDP growth in 2018<sup>3</sup>.

Leading in GDP growth are APAC's two largest emerging economies, India and China, which are projected to witness strong GDP growth rates in the short to mid-term. India's real GDP is forecast to register a growth rate of 7.4 percent in 2023, primarily owing to strong growth in private consumption driven by positive labor market conditions. China, on the other hand, is projected to witness a growth rate of 5.6 percent in real GDP in 2023, owing predominantly to continuation of government initiatives aimed at stimulating domestic consumption and infrastructure development.<sup>5</sup>

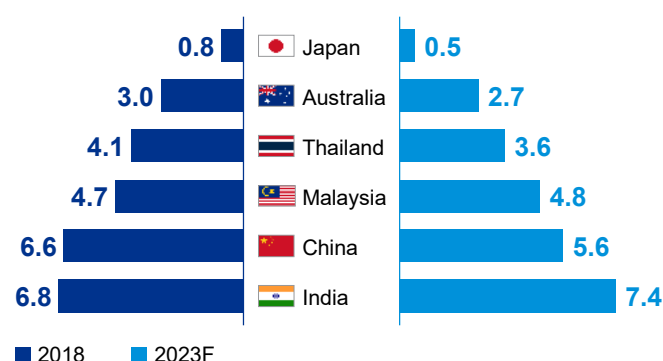
Adding further momentum to the overall growth story in the region are the emerging upper-middle income economies of South East Asia — Malaysia and Thailand. Both the nations are touted to experience strong private consumption during the short to mid-term, which is likely to be triggered by an increase in job opportunities in their respective labor markets.<sup>6</sup>

Conversely, while developed economies, Australia and Japan, are also projected to experience reasonable GDP growth rates during the forecast period.

Graph 1. GDP at current prices (US\$ trillion), 2018 and 2023F<sup>4</sup>



Graph 2. Real GDP growth rate (%), 2018 and 2023F<sup>4</sup>



3. "Asia's economy remains the world's growth engine, accounting for 62% of global GDP growth", Asia Law Portal, [Link](#)

4. GDP by Country, Statistics from IMF, 1980-2024, Knoema, [Link](#)

5. "We've entered the Asian century and there is no turning back", World Economic Forum, [Link](#)

6. "Economic Outlook for Southeast Asia, China, and India 2019", OECD, [Link](#)



With strong economic forecasts, a rising middle class and a desire for more advanced medical services in the major emerging markets, the demand for advanced medical devices in the short to mid-term is expected to grow in line with or above broader market and sector expectations.

A combination of continuous low inflation and low & declining unemployment rates represent positive socio-economic factors that are likely to support growth of the overall healthcare industry in APAC.

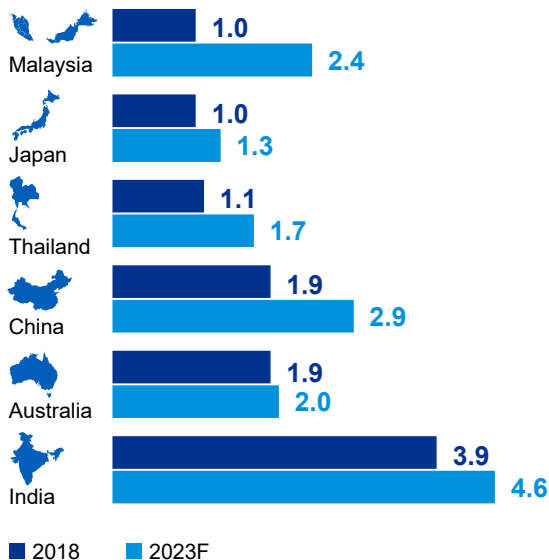
**A backdrop of continued benign inflation and robust economic growth has positioned APAC countries at a sweet spot in the global economy.** During 2017–18, inflation forecasts across majority of the region have either been kept constant or revised down. Weaker import prices, including low commodity prices, are the primary reason why core inflation has fallen short of government estimates in APAC countries.<sup>8</sup>

Going forward, it is estimated that core inflation in APAC may rise as temporary factors such as commodity prices increase in the near term.<sup>9</sup>

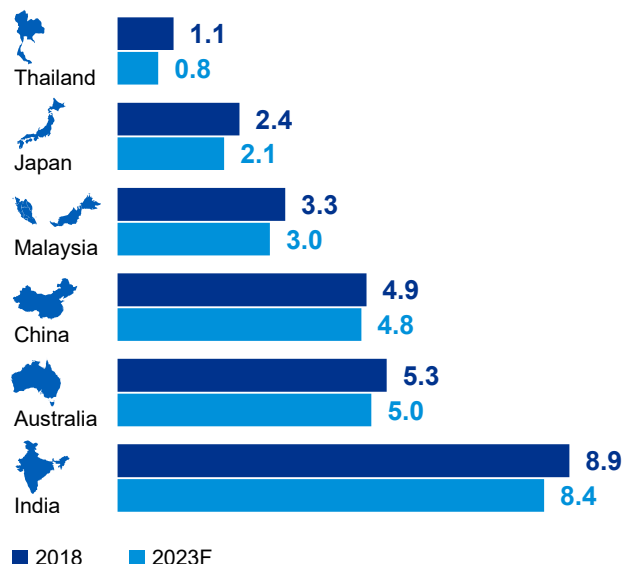
In addition to low inflation, unemployment rate in APAC has also remained considerably low compared to global estimates, a trend that is expected to remain steady in 2020.<sup>10</sup>

Consequently, a combination of low inflation and declining unemployment rates in APAC is indicative of a positive social and economic environment that supports the growth of and investment in the overall healthcare industry, including medical devices.

**Graph 3. Average consumer prices inflation (%), 2018 and 2023F<sup>7</sup>**



**Graph 4. Unemployment rate (%), 2018 and 2023F<sup>7</sup>**



7. The Economist Intelligence Unit

8. "Low Inflation in Asia: How Long Will It Last?", Sipotra, [Link](#)

9. "Signs Point To Stronger Commodity Prices In 2020", Seeking Alpha, [Link](#)

10. "Employment and unemployment in Asia-Pacific: Trends and projections", International Labor Organization, [Link](#)



## 2.2 APAC's dynamic demographic forecasts

### The forecast population growth of the region herald the start of the Asian Century

While economists and political scientists have talked for decades about the coming of the Asian age, the year 2020 sees the world's imminent entry into what many have termed as the "Asian Century".<sup>11</sup>

APAC's two most populous countries, **India and China**, offer a combined population of more than **2.8 billion** or **38 percent of world population**. While India comprises a greater share of young and growing individuals, China's population is aging rapidly. This is primarily due to the long-term effect of China's population control policy, indicating that the country will soon enter an era of "negative population growth".<sup>13</sup>

While the smaller South East Asian countries, Malaysia and Thailand, are less densely populated by comparison, both the nations have been experiencing a rapid growth in their middle class combined with growing entrepreneurial flair of businesses, creating two of the most dynamic markets in the world. Interestingly, these markets are also set to witness their aging population increase steadily in the coming years.

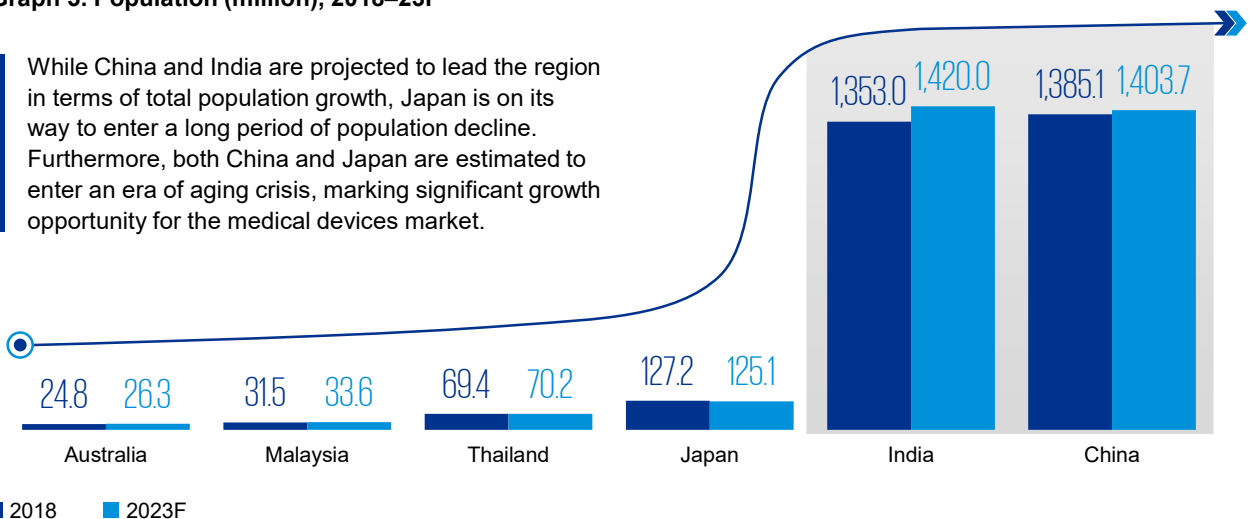
It is estimated that by 2020, the number of people aged 65 years and above will constitute over 13 percent<sup>14</sup> and 7.2 percent<sup>15</sup> of the total Thai and Malaysian population respectively. In 2015, Japan's total population stood at over 127 million, however, the country is on its way to enter a long period of population decline. It is estimated that the population will reduce to around 110.9 million by 2040, and fall below 100 million by 2053, indicating a significant demographic shift in the future. It is likely that the proportion of the elderly out of the entire population will grow from 26.6 percent in 2015 to 33.3 percent by 2036, corresponding to one in three people being elderly in Japan.<sup>16</sup>

Australia's population, on the other hand, has been growing steadily over the past decade. This is largely due to an existing positive economic climate that has resulted in increased overseas immigration. Despite the high rate of population growth, Australia is also seeing its population age, though not as rapidly as other wealthy countries.<sup>17</sup>

Overall, the twin factors of a growing middle class and an aging population marks the starting point for strong demand of advanced medical devices in the Asia-Pacific region.

Graph 5. Population (million), 2018–23F<sup>12</sup>

While China and India are projected to lead the region in terms of total population growth, Japan is on its way to enter a long period of population decline. Furthermore, both China and Japan are estimated to enter an era of aging crisis, marking significant growth opportunity for the medical devices market.



11. "The Asian century is set to begin", Financial Times, [Link](#)

12. The Economist Intelligence Unit

13. "India to overtake China as most populous country within a decade, UN report finds", Independent, [Link](#)

14. "Proactive measures needed to cope with ageing society", The Nation Thailand, [Link](#)

15. "A holistic approach to ageing needed in Malaysia", The Start, [Link](#)

16. "Population projections for Japan", National Institute of Population and Social Security Research, [Link](#)

17. "Older Australia at a glance", Australian Institute of Health and Welfare, [Link](#)

## Increased life expectancy and rapidly aging populations speak to a significant growth opportunity for life sciences companies including medical device companies

Increase in average life expectancy combined with significant fall in fertility rates in APAC have resulted in countries, especially Japan and China, experiencing an aging population, a process expected to continue in the coming decades.

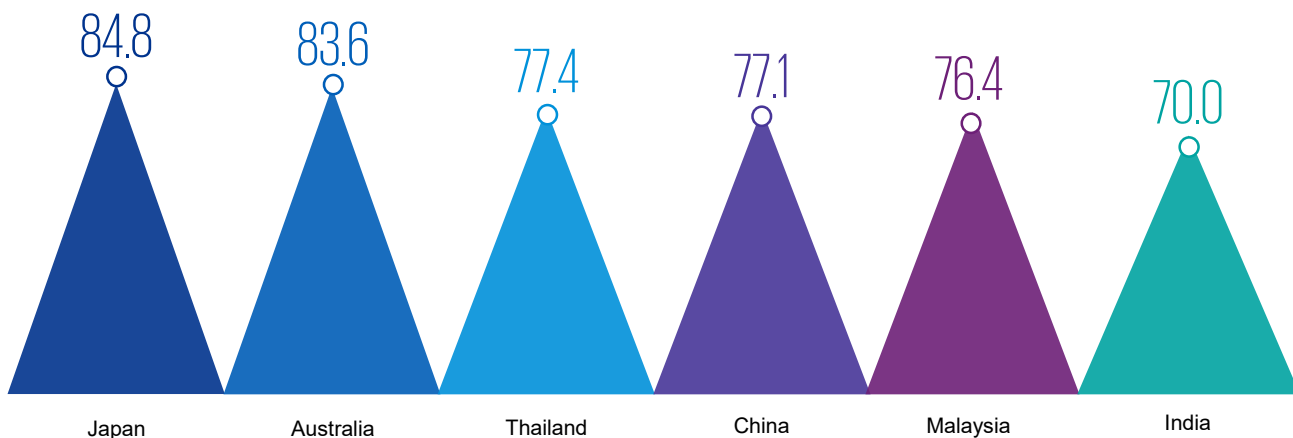
For life sciences companies, the opportunity to support aging populations in both developed and emerging markets is significant while there is also significant scope to support the emerging markets as the need for critical services increases with aligned investment in infrastructure, medical services and professional medical training.

The scale and complexity of such problems point to the potential opportunities for the government and the private sector to enhance healthcare systems. Governments play a key role in creating awareness and accessibility of health treatments and tools to overcome the problem of widely prevalent but manageable health issues. Public-private partnerships could further take actionable steps to ensure widespread accessibility of early diagnostic capabilities to bridge the gap between the developed and developing nations.

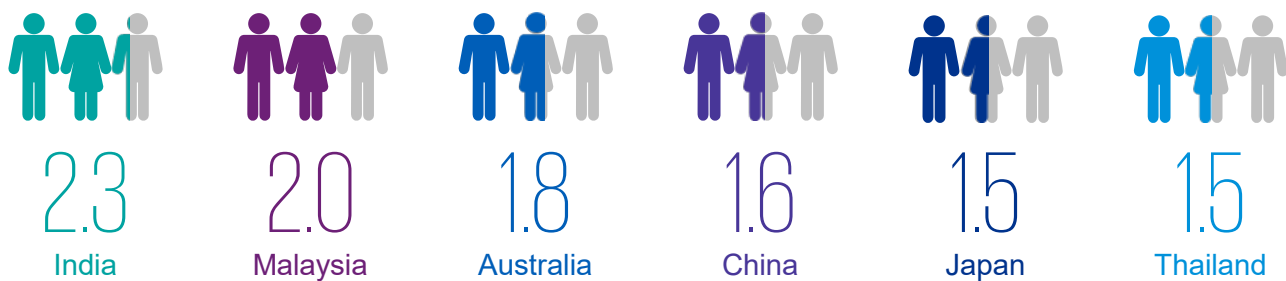
A parallel flow in healthcare spending, both public and private, is crucial to maintain the economic healthcare balance in a country.

## Comparison of APAC countries on demographic indicators:

Graph 6. Average forecast life expectancy (years), 2023F<sup>18</sup>



Graph 7. Total fertility rate, 2019<sup>19</sup>

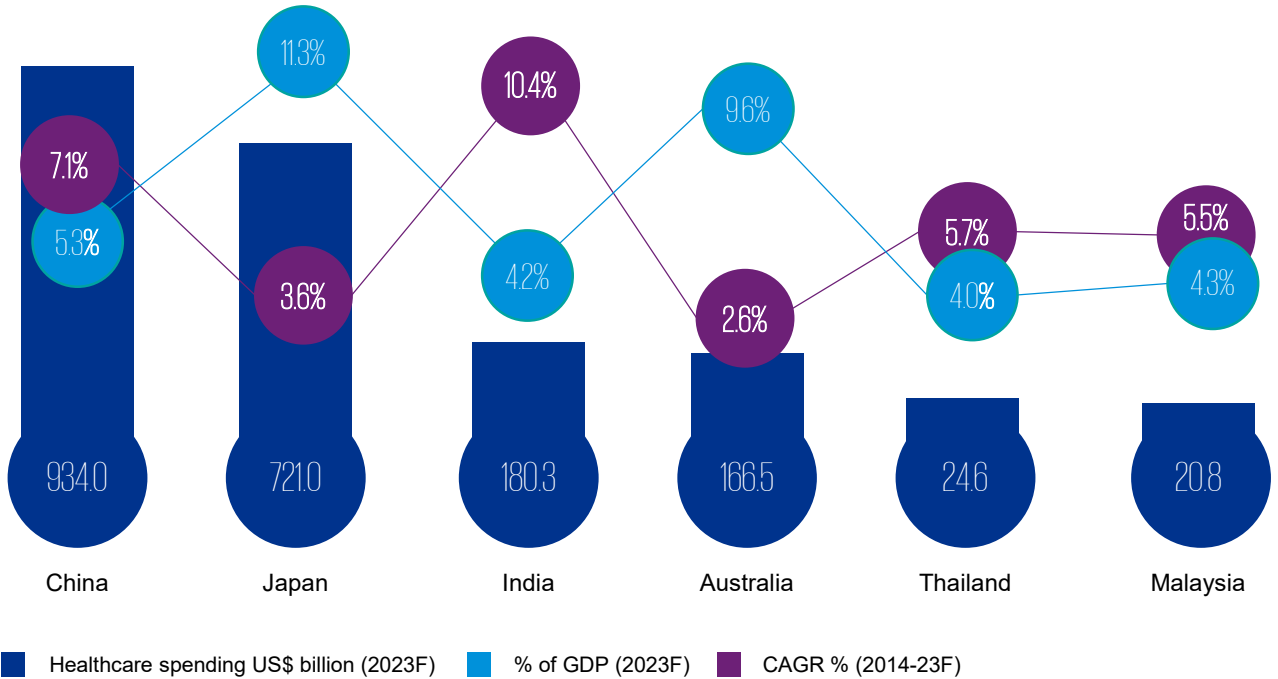


Note: Fertility rate is the average number of children born to per woman of the childbearing age (15–44 years)

18. EIU 2019 reports of all six countries

19. "Total Fertility Rate 2019", World Population Review, [Link](#)

**Graph 8. Healthcare spending (US\$ billion,%,%), 2014–23F<sup>20</sup>**



## Long road ahead for healthcare spending in APAC

In almost all of APAC, the growth in healthcare spending has been outpacing the growth in GDP, indicating that the ultimate burden of healthcare cost is growing faster than the economic ability of a nation to sustain it.

To try and combat this dynamic, governments have been launching new healthcare initiatives, for instance, national health plans such as Ayushman Bharat - National Health Protection Scheme (AB-PMJAY) in India and Healthy China 2030 in China.

Much of the growth in Malaysia's and Thailand's healthcare expenditure stems from healthcare inflation coupled with continued expansion in the central government's budget allocation to the health ministry.<sup>21</sup>

While the region exhibits factors supporting the growth of healthcare and medical devices market, it also indicates that APAC countries may face challenges funding the increasing healthcare requirements of their respective populations.

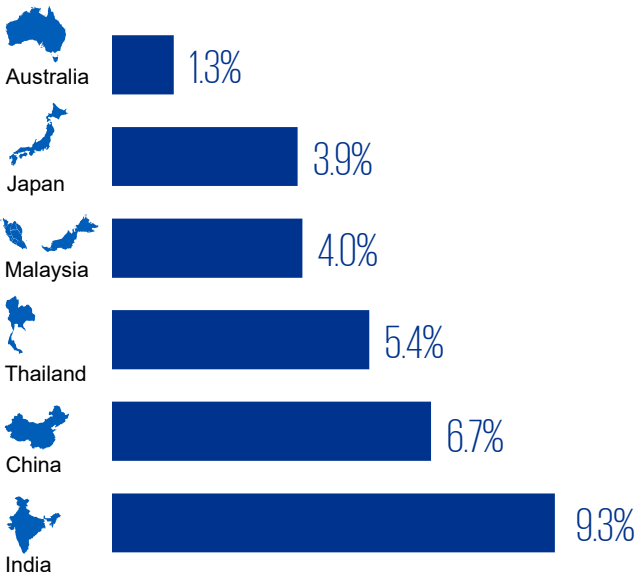


20. EIU 2019 reports of all six countries

21. "The ~USD 320 billion healthcare challenge in ASEAN", Solidiance, [Link](#)



**Graph 9. Growth in healthcare spending per head (%), 2014–23F<sup>22</sup>**

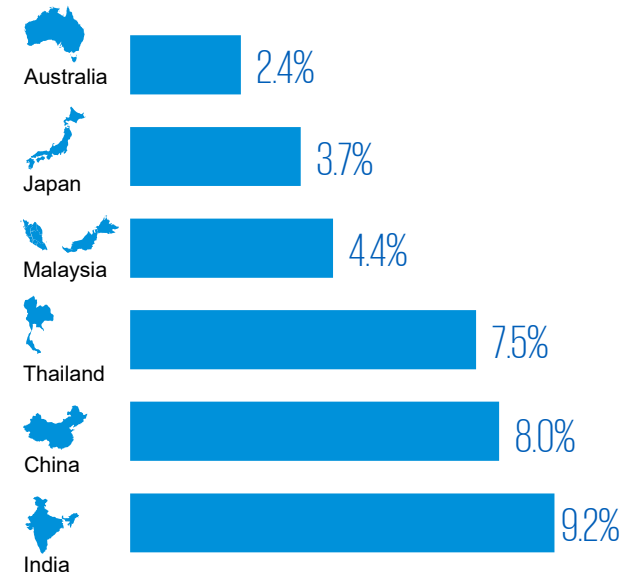


A strong national healthcare system typically sees the government support between 70-80 percent of medical expenses with the remainder borne by the patient. For APAC, out-of-pocket spending on healthcare is relatively low in Thailand, Japan and Australia.

In India, despite the government’s recent efforts, out-of-pocket expenses continue to remain high, with patients spending almost double of what the government spends on them.

<sup>22</sup>. EIU 2019 reports of all six countries

**Graph 10. Growth in consumer healthcare expenditure (%), 2014–23F<sup>22</sup>**



While governments and value chain stakeholders have undertaken several steps to bridge the gap between healthcare expenditure and access, quality and affordability continue to remain a work in progress for APAC countries. Hence, governments in the region must learn to refocus their healthcare efforts toward providing affordable care through advanced medical facilities and medical equipment that are accessible to the masses.

## 2.3 Managing the workforce and infrastructure demand

With an aim to bridge the healthcare demand and supply, medical devices companies can find an avenue to expand their presence in APAC.

**Graph 11. Number of doctors (per 1,000 people), 2023F<sup>22</sup>**



**Graph 12. Number of hospital beds (per 1,000 people), 2023F<sup>22</sup>**



Australia's performance within APAC, when it comes to the number of doctors and nurses per population, is exceptional. The country surpasses the likes of Canada, the UK and New Zealand, owing to the doubling of the number of medical schools and almost tripling of the number of medical graduates over the past decade.<sup>23,24</sup>

On the other hand, there is an acute shortage of healthcare workforce in Thailand and India. It is estimated that the global healthcare workforce shortage would reach 80.2 million, of which India would face a shortage of 2 million doctors and 6 million nurses by 2030.<sup>25</sup>

To combat these issues, the Indian healthcare sector plans to generate nearly 40 million new jobs by 2020 through several government schemes and programs. Ayushman Bharat, India's largest healthcare program, is expected to be a key contributor in the growth of healthcare job creation in the country. On similar lines, the Thailand National Digital Healthcare Workforce Development Initiative (WDI) was launched with a focus on development of a three-year work plan to address the demand of patients for digital healthcare services in light of the country's workforce shortage.<sup>26</sup>

While strong physician and hospital bed availability is an advantage for Australia and Japan, these countries are also witnessing a rapid increase in aging population and healthcare needs in rural areas. This, in turn, signals that apart from human resources, advanced diagnostic and medical tools, to enable quicker diagnostics and treatment, are acute needs across the region.

22. EIU 2019 reports of all six countries

23. "How can Australia have too many doctors, but still not meet patient needs?", The Conversation, [Link](#)

24. "Healthcare Resource Guide: Australia", Export.gov, [Link](#)

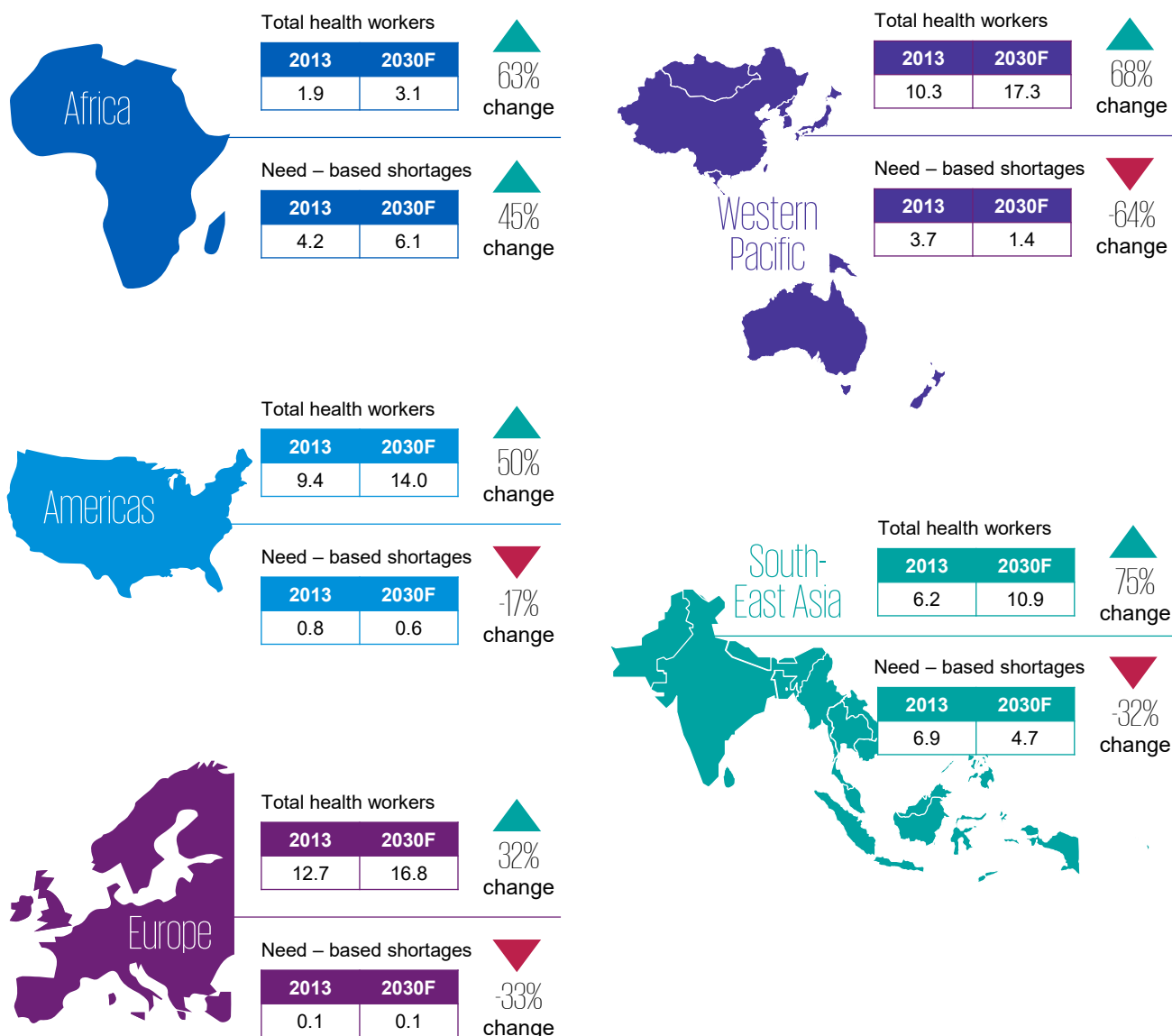
25. "By 2030, India will need 2 m doctors, 6 m nurses", Business Line, [Link](#)

26. "Indian healthcare industry to employ millions by 2020", Live Mint, [Link](#)

Globally, the total health workforce is expected to reach 67.3 million by 2030. Amongst this, South East Asia accounts for 10.9 million. This is a 75 percent increase from 6.2 million in 2013.

The need-based shortage of healthcare workers is quite high in South East Asia, owing to high share of global population that the regions holds. While projections do indicate a shortage of 4.7 million health workers by 2030, there is a sharp decline of 32 percent, from 2013 to 2030F, indicating the massive impact of policies, regulations and initiatives aimed toward reducing the shortage of healthcare workers by 2030.

**Graph 13. Total health workers and need-based shortages (in millions), 2013 and 2030F<sup>27</sup>**



27. "Global strategy on human resources for health: Workforce 2030", WHO, [Link](#)

# 3. Medical devices industry analysis



# 3.1 APAC medical devices market aiming to dominate globally

## The APAC medical devices landscape is evolving and growing rapidly

The APAC region is comprised of a number of varied markets. While it is home to some of the most advanced healthcare systems, it also includes areas where access to healthcare is relatively limited. Some of the sharpest disparities can be found in the market for medical devices in these countries. A rapidly aging population, universal health insurance coverage and a strong regulatory network has positioned Japan as one of the frontrunners for medical devices globally.

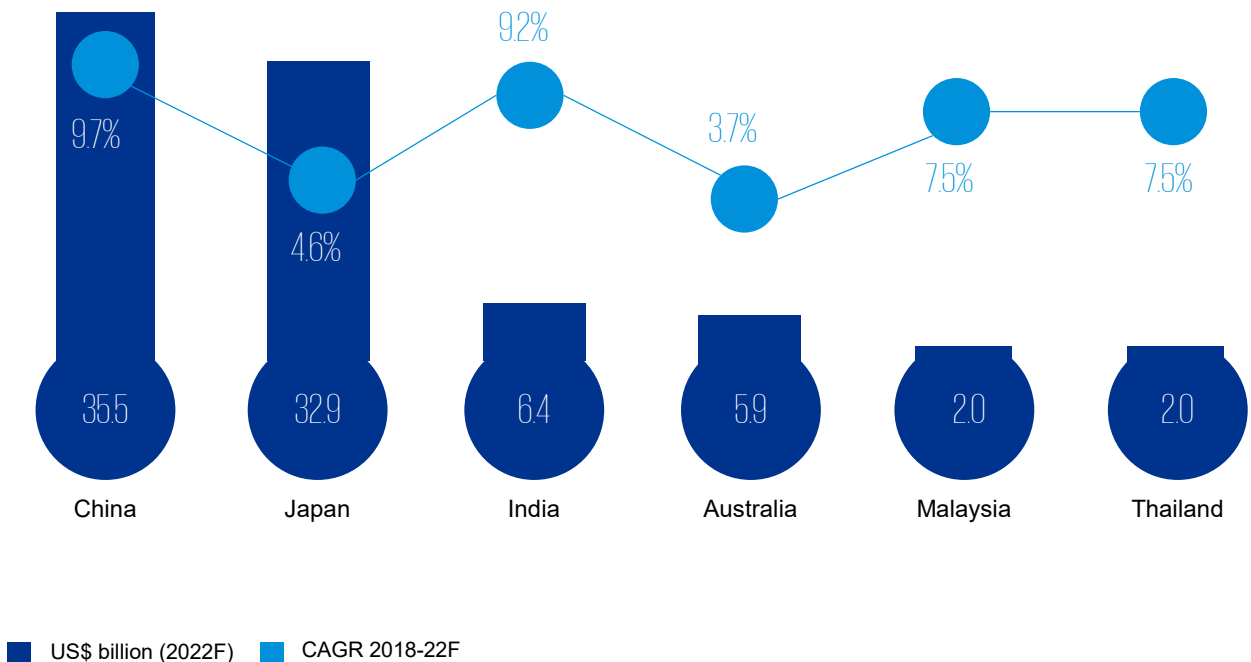
In China, the government's efforts to simplify the regulatory system for overseas investors, an expedited approval process for innovative products, agreements to cut tariffs on imported high-tech devices and relaxation of procurement controls on

certain equipment are some of the key enablers pushing for an almost double-digit growth for the country, the highest in the region.

While Japan and China are relatively more mature, the remaining nations are on their way, picking up pace, to make their mark in the international arena. An expanding middle class supporting the development of the private sector, improving medical devices regulations and growing medical tourism are key factors driving the growth for these developing markets.

Although independently, these countries have their respective enablers driving growth in the market, a commonality among all of them is the strong import and export network, helping APAC make its presence felt globally.

Graph 14. Medical devices market in APAC (US\$ billion, %), 2022F and 2018–22F<sup>28,29,30</sup>



Note: The figures for China, India, Malaysia and Thailand have been sourced from Fitch Solutions reports while those for Australia and Japan have been sourced from different reports as we did not find consolidated reports for these countries. 2023F figures for Japan and Australia have been calculated.

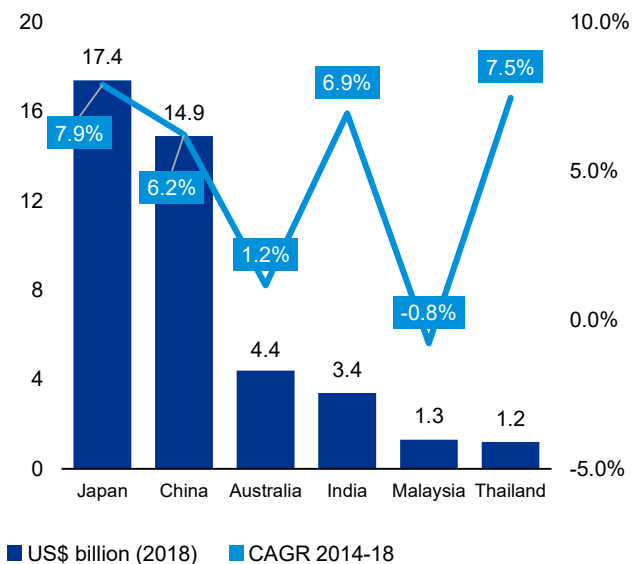
28. Fitch Solutions medical devices report for China, India, Malaysia and Thailand

29. "Australia - Medical Devices", Export.gov, [Link](#)

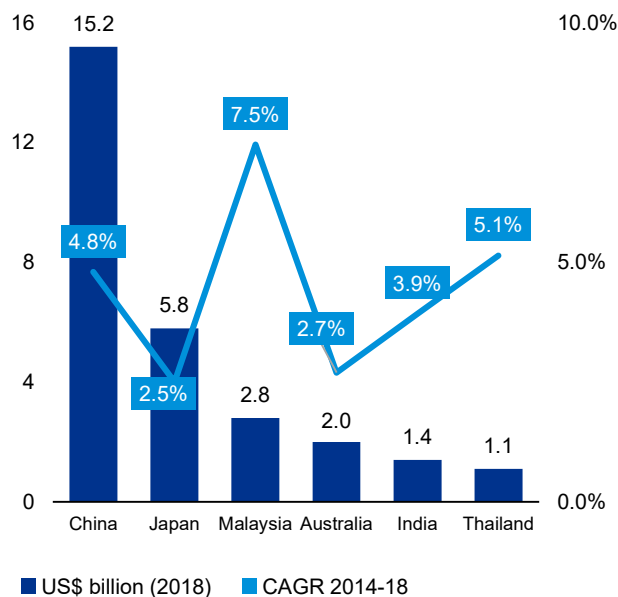
30. "Worldwide medical device market forecasts", Fitch solutions report



**Graph 15. Medical devices imports (US\$ billion, %), 2018 and 2014–18**<sup>31,32,36</sup>



**Graph 16. Medical devices exports (US\$ billion, %), 2018 and 2014–18**<sup>31,32,36</sup>



A high dependency on the US market, over 20 percent, for advanced medical devices is a key driver for high import growth in APAC countries.

While India, Thailand and China are major importers of orthopaedics and prosthetics devices, US imports in Malaysia are skewed toward other medical devices such as diagnostic imaging equipment.

Over half of all imports for Australia originate from the US and Germany. This speaks to demand for high-quality, sophisticated and advanced technologies that are being integrated into the next generation of medical devices.

Imported medical devices account for 49 percent of the total market in Japan. In the coming years, the market is expected to remain heavily dependent on imported advanced medical technologies, especially due to high demand for quality products from senior citizens in their later years of life.<sup>33,34</sup>

The robust growth in export of medical devices indicates the expanding domestic market in the APAC region.

Consumables and diagnostic imaging have been the clear frontrunners for global export demand, primarily from India and China. Over a third of the exports are sent to the EU. Germany has been a leading destination, receiving over 15 percent of the exports.

In May 2019, the US government imposed high import tariffs on Chinese goods including medical devices such as diagnostic reagents used in X-rays and imaging equipment, to name a few. This has resulted in significant trade tensions between the two countries.<sup>35</sup>

The trade concerns have particularly been challenging for device manufacturers that operate across the two countries, as they now have to pay taxes at multiple points.

Note: The figures for China, India, Malaysia and Thailand have been sourced from Fitch Solutions reports while those for Australia and Japan have been sourced from different sources as we did not find the Fitch report for Australia and Japan.

Currency conversion: 1JPY=US\$0.00917, as on 29 January 2020, [www.oanda.com](http://www.oanda.com)

31. "Fitch Solutions report for China, India, Malaysia and Thailand"

32. "Australia's medical equipment trade from 2014 to 2018", Statista, [Link](#)

33. "Rising demand for medical device imports in Japan", WEDC, [Link](#)

34. "Healthcare Resource Guide: Japan", Export.gov, [Link](#)

35. How is the US China trade war hitting the medical device industry?", Medical Device Network, [Link](#)

36. "Japan medical device imports and exports", Statista, [Link](#); [Link](#)

# 3.2 The evolving medical devices distribution network

## Distribution is the new manufacturing

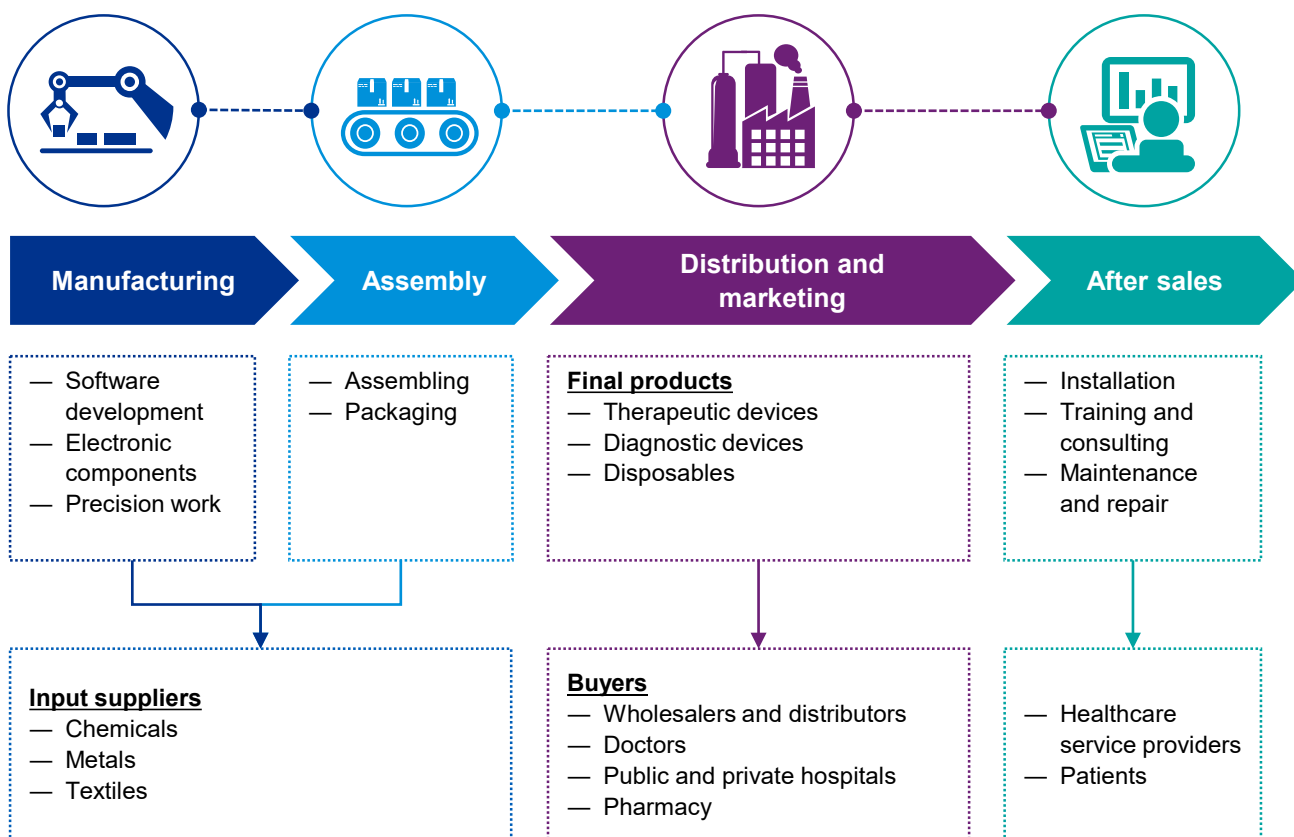
APAC has always been a relatively tough geography for foreign investors to enter with respect to medical devices.

Traditionally, firms have struggled with issues such as stringent regulatory policies and complex tender procedures to procure medical devices. Governments across APAC are working towards strengthening their regulatory system, making it more inclusive and holistic.<sup>37</sup>

Distribution plays a key role in the entire medical devices supply and distribution network. Each stakeholder in the network is responsible for their specific functions including sourcing, procurement, transportation, storage and maintenance.

As dynamic as the APAC countries are in their approach to healthcare systems, their distribution networks also vary significant in terms of capability, scale and maturity.

## Medical devices value chain



37. "Medical Device Market in 2016: Challenges In The Traditional Markets And New Opportunities In Asia Pacific", Euromonitor International, [Link](#)

## Distribution network in Japan

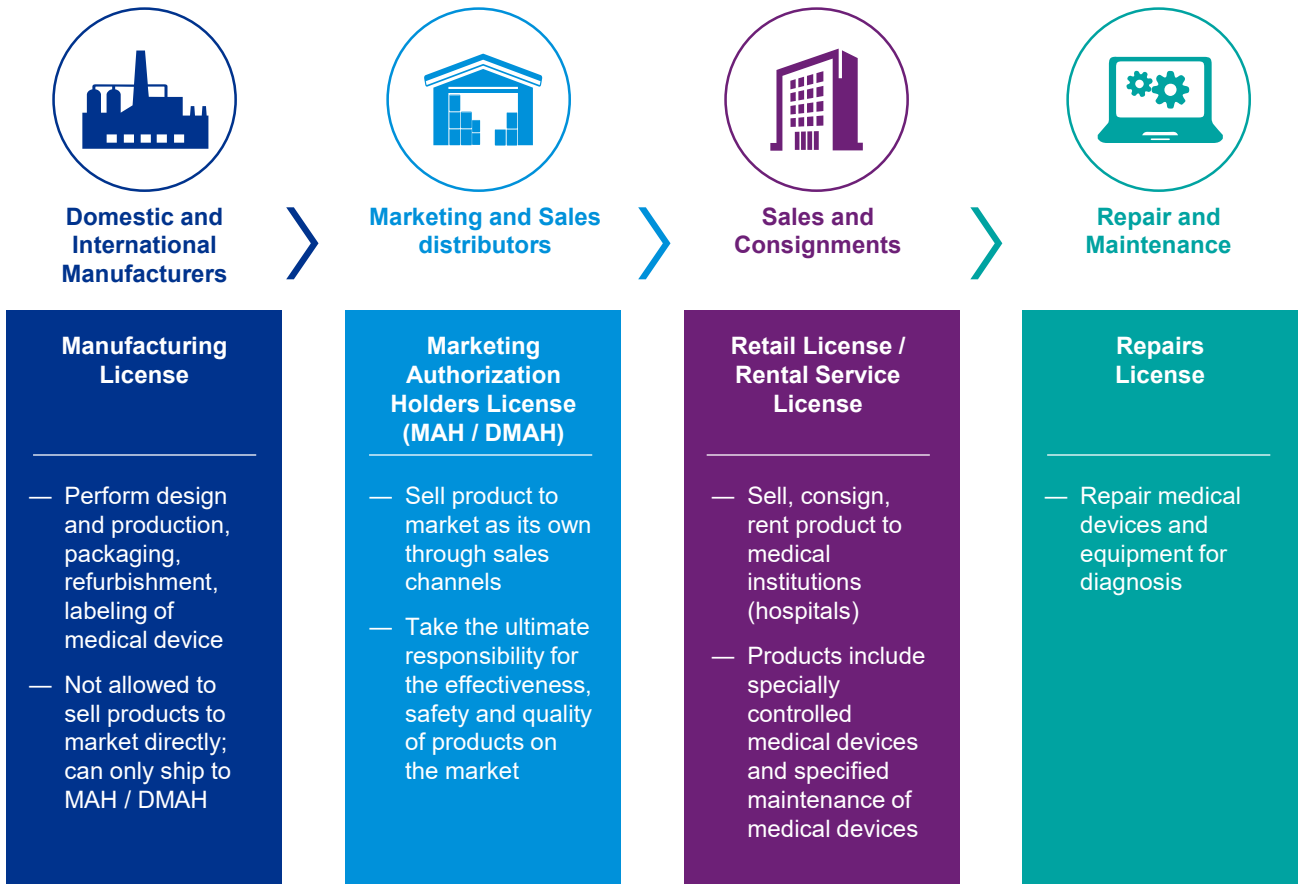
Japan has for long been quite a complex but lucrative market for foreign companies to enter and distribute their medical devices. The distribution network involves intricate and interdependent partnerships among various participants. However, reimbursement rates which are systematically reduced by the Japanese government, impose all participants of the value chain to streamline the distribution process.

There are nearly 2,500 medical device and equipment dealers in Japan. Hospitals primarily procure medical device and equipment through one dealer, known as a **“hospital-linked dealer”**. This is done in order to simplify the procurement processes. Along with the hospital-linked dealer, there are other agents as well.

Essentially, the relations between a dealer and hospitals and doctors are quite close and tight-knit, which could lead to a monopolistic situation in the market. Hence, instead of establishing a subsidiary in the country, companies tend to focus on establishing relationships with regional partners/doctors.

In medical devices distribution, there are five types of licenses for each business, and manufacturing and sales licenses are ultimately responsible for distribution in the Japanese market.<sup>38</sup>

## Product distribution flow of medical devices and required licenses<sup>39</sup>



38. “Brief Guide for European Companies on Importers and Wholesale Distributors in Japan (food and wine; ICT; medical devices)”, EU-Japan.eu, [Link](#)

39. Pharmaceuticals and Medical Device Agency (PMDA), [Link](#)

Sales and shipment of Japanese medical equipment to hospitals are essentially managed through agents. Depending on the product, there are two models of sales — a **sell-out model with a discount** and a **consignment model that charges for only the amount used**.

### Sell-out model

A form to sell in response to MD-Net (MD-Net is EDI order of medical device.) or order from a distributor. All shipments are billed, but customary discounts are calculated based on the number of goods sold from the agency to the end-user hospital. This format is used for simple medical devices such as surgical consumables



### Consignment model

It is divided into a long-term type format that is always deployed in the hospital as holding stock, and a short-term type that is deployed in accordance with surgery, etc. However, under this model only the used goods are charged out of the total shipment. This model is used for highly managed medical devices used in surgery, etc.



Other players in the medical devices value chain in Japan that play a key role are **third-party logistics players (3PLs), distributors, forwarders, distributors as contractors and distributors from the manufacturers**

**Nearly 80 percent of sales are facilitated through a dealers.** However, when it comes to dealing with larger and more expensive medical equipment for public medical institutions, central government and other public entities, deal directly with manufacturers through open bidding.<sup>40</sup>

40. "Local Agent Representation for Medical Products in Japan (DMAH)", Pacific Bridge Medical, [Link](#)

## Role of each entity in the medical devices distribution value chain<sup>41</sup>

Entity	Role
<b>Forwarder</b>	— Since overseas medical devices are manufactured overseas, a forwarder imports them. In addition, it creates and stores customs clearance and incidental customs records
<b>3/4PLs</b>	— They are entrusted to a medical devices manufacturer and take charge of ordering, inventory management, and shipping based on warehouse management — For medical devices, legal labeling is regarded as a manufacturing act, hence, they also hold a manufacturing license
<b>Delivery company</b>	— It is responsible for transporting products from airports and ports to DC (distribution center) and any small-scale transport from DC to distributors or hospitals
<b>Dealer (Agent)</b>	— It is responsible for making orders from hospitals, delivering to hospitals, and generating invoices. Orders from hospitals, including rental cases, are basically communicated to medical devices manufacturers through agents. They are also responsible for product introduction, order receipt, delivery, sales collection, and aftercare

## Role of Marketing Authorization Holder

In Japan, a local unit which has been designated as a Marketing Authorization Holder (MAH) or a Designated Marketing Authorization Holder (DMAH) has the authority to import and sell medical products. This network has been put into place to so that all companies importing imported medical devices to Japan have a local entity that can take complete accountability for products.

MAH is an entity based locally in the country and has the marketing authorization license. It is responsible for registration of the product and owns the approval certificate. Conversely, if a foreign company that wishes to distribute product in Japan but does not have a local office in the country, can partner with a DMAH.

## Responsibilities of MAH/DMAH<sup>42</sup>



Supervising manufacturing



Handling product registration and approval



Managing product quality and safety



Managing storage and administering distributors



Ensuring post-market surveillance

41. "Medical Industry Structure Reform, 2019", Yano Research Institute Ltd., published on 31st January 2019

42. "Local Agent Representation for Medical Products in Japan (DMAH)", Pacific Bridge Medical, [Link](#)

## Distribution network in Australia

The Australian government is the key buyer of medical devices for hospitals in the market. Public hospitals essentially account for about 70 percent of purchases, while private sector accounts for the remaining 30 percent.

## Role of distributors in the market

The distribution network of a medical device in Australia is primarily held by the Original Equipment Manufacturer (OEM) itself. They have their own system of operations and hold primary control over the market. However, a key role is played by 3PLs, especially DHL, which has a strong market presence in Australia. The role of these 3PLs is primarily restricted to transportation and logistics.<sup>43</sup>

Another key entity in the market is a 'sponsor'. A sponsor essentially acts as a liaison between a foreign medical device company and the medical device regulatory body in the country, Therapeutic Goods Administration (TGA). It is responsible for import of foreign medical devices, export of Australian devices and assumes regulatory representation for these foreign medical devices.<sup>44</sup>

## Digital health strategy and its role in supply chain

With the aim of improving health status for Australians by providing digital healthcare systems and focusing on their national digital health strategy, in July 2016 the Australian government established the **Australian Digital Health Agency**. The Agency is accountable for providing digital health services in the country with key emphasis on innovation, quality and safety.

Recognizing the bottlenecks in the overall healthcare supply chain network due to lack of standardized product location and identification assessment, leading to avoidable losses, the Agency established the **National Product Catalogue (NPC)**, which is a central source of standardized information on medical products. It is also equipped with an **eProcurement** solution which has been created to simplify the electronic purchasing process.<sup>45</sup>



43. "Supply Chain", Digital Health, [Link](#)

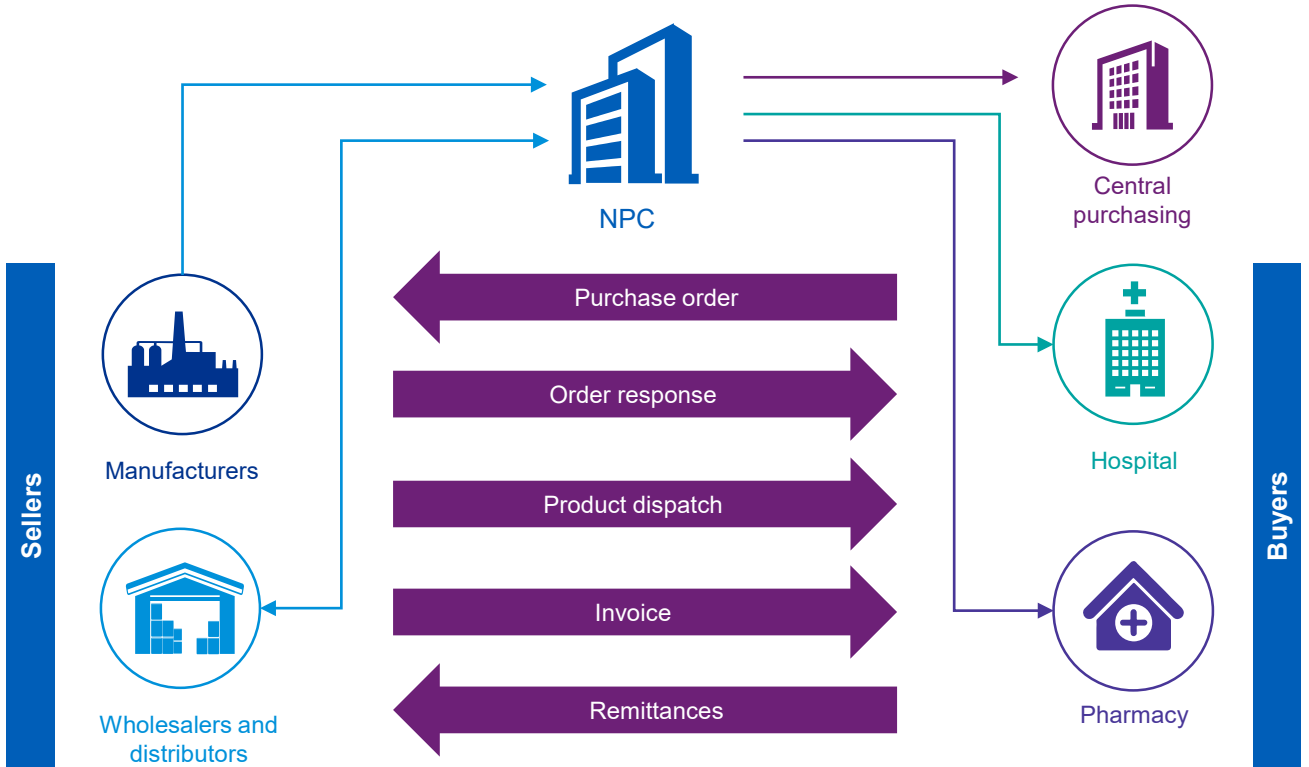
44. "Public Hospital Device Procurement", MTA, [Link](#)

45. "Role of a sponsor", TGA, [Link](#)

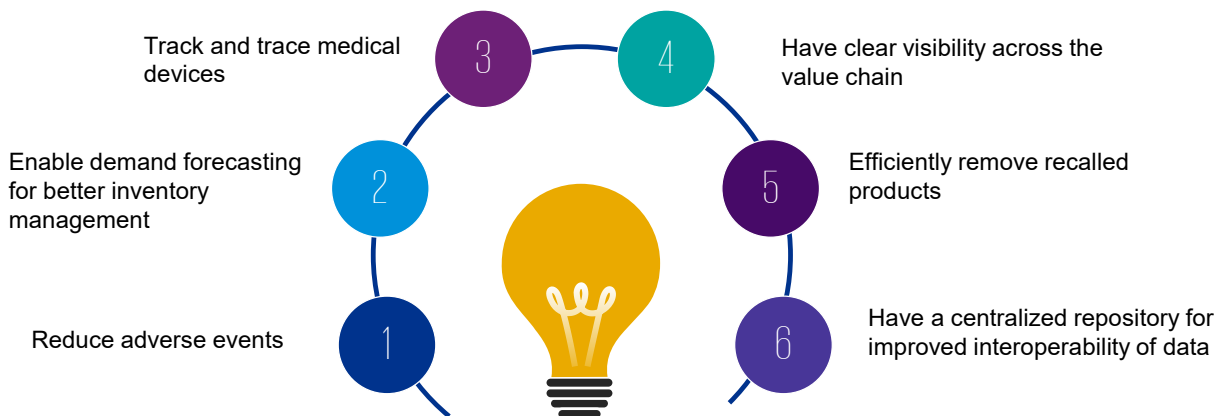
**eProcurement system<sup>46,47</sup>**

The eProcurement process utilizes unique identifiers (Global Trade Item Numbers) for medicines and medical devices and unique location identifiers (Global Location Numbers). With standardized data delivered by the National Product Catalogue (NPC), this eProcurement system

aims to improve the overall productivity of the procurement process and in turn helps reduce overall costs. This process benefits buyers and as well as suppliers by reducing probability of technical errors and enhancing the product visibility and traceability across the supply chain network.



**Benefits to be attained**



46. "eProcurement", Digital Health, [Link](#)

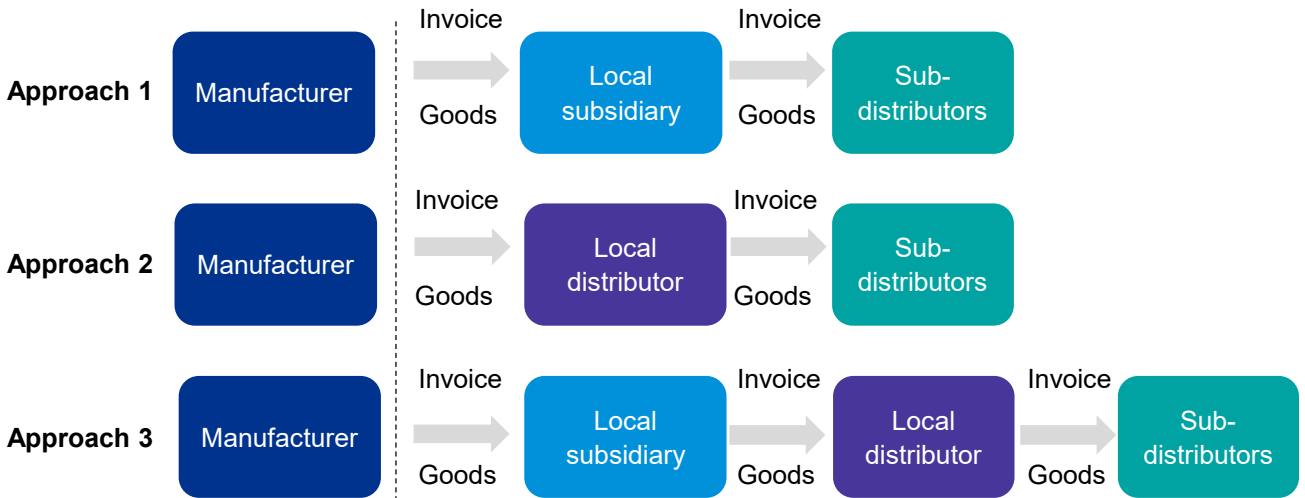
47. "National Product Catalogue", Digital Health, [Link](#)

## Distribution network in China

China's distribution is regionally-based and highly fragmented. Relationships are key to distribution in the medical devices market due to the nature of the healthcare system in China. There are quite a few distributors in the market with coverage limited to one or two segments of a hospital in a city. Distributors often partner with other sub-distributors to increase their coverage, thereby splitting margin along the value chain.

## Traditional distribution model<sup>48</sup>

Through this context, medical devices manufacturers, especially international companies, traditionally have three avenues to approach the distribution network in China. These three approaches are as follows:



An international medical devices manufacturer has the choice to distribute its product by creating a local subsidiary/wholly foreign owned enterprises (WFOEs) in China and keep the network in-house. The company also has the option of directly working with a local Chinese distributor and leveraging its established network. Lastly, the company has the option of collaborating its local subsidiary with a local Chinese distributor.



48. "Choosing a Distribution Model for the Chinese Market", China Briefing, [Link](#)



Following are the pros and cons of each approach taking into consideration the relevant corporate structures, costs, tax liability, customs procedures and intellectual property (IP) risk

	Approach 1 (only local subsidiary)	Approach 2 (only local distributor)	Approach 3 (both local subsidiary and distributor)
<b>Description</b>	<ul style="list-style-type: none"> <li>Local subsidiary is responsible for selling goods.</li> <li>Subsidiary completes customs clearance, payment and develops client relationships in China.</li> </ul>	<ul style="list-style-type: none"> <li>Local distributor receives goods and is responsible for sales.</li> <li>It completes all the customs formalities and manages client relationships.</li> </ul>	<ul style="list-style-type: none"> <li>Local distributor serves as the importer and is responsible for customs clearance.</li> <li>Subsidiary develops client relationships and lends logistics support.</li> </ul>
<b>Pros</b>	<ul style="list-style-type: none"> <li>Maximum net profit for manufacturer</li> <li>IP protection and security of goods are increased.</li> </ul>	<ul style="list-style-type: none"> <li>Maximum net profit and minimum net tax liability for subsidiary</li> <li>Less amount of supervision required and distributor has an established network.</li> </ul>	<ul style="list-style-type: none"> <li>Easier logistics and lower financial pressure</li> <li>Lesser control required as compared to approach 2</li> </ul>
<b>Cons</b>	<ul style="list-style-type: none"> <li>Maximum tax liability for subsidiary</li> <li>Manufacturer must manage cash flow due to unforeseen clearance expenses.</li> </ul>	<ul style="list-style-type: none"> <li>Pricing system is highly influenced due to the role of distributor.</li> <li>IP protection and security are more difficult due to lack of local presence.</li> </ul>	<ul style="list-style-type: none"> <li>Manufacturer might have to shell out partial sales profit to ensure smooth flow of sales.</li> </ul>

### New distribution model<sup>49,50</sup>

With over 12,000 distributors in China’s medical devices market, distribution tends to be a complex task for manufacturers. This is because:

- **China’s distribution network is quite disintegrated:** despite numerous distributors in the market, their coverage is usually limited to few hospitals
- **Lack of strong distributor relationships:** it is quite difficult for hospitals or procurement entities to verify and determine reliable local distributors that have significant coverage in a region
- **Lack of an initiative to expand market:** Chinese distributors are usually concentrated existing partnerships and channels and tend to ignore developing the market for new innovative products

The government and regulators recognized the need for consolidation of the fragmented medical devices market and improve supply chain transparency. In December 2016, the government introduced the “**Two-Invoice System**” policy with the aim to eliminate sub-distributors and other intermediaries from the medical devices supply chain. This system required Chinese distributors to make **a maximum of two transactions — one with the device manufacturer and the other with the hospital.**

49. “The Key to Successfully Selling Medical Devices in China and Japan – Good Distributors”, Pacific Bridge Medical, [Link](#)

50. “Best Strategies for Distributor Search in China”, MedTech Intelligence, [Link](#)

The government aims to generate **three main advantages from this policy**:<sup>51</sup>



Reduce the number of intermediaries and consolidate market



Increase the overall transparency and efficiency



Reduce distribution costs and fraudulent activities for hospitals

### Long-term impact of Two-Invoice System<sup>52</sup>

The Two-Invoice system will have significant impact in the long run, across all the stakeholders of the value chain. It is expected that existing large and medium-sized distributors will dominate the market, while smaller, domestic distributors and sub-distributors will be forced to exit. While the policy is still in its early stages and its full impact is yet to be determined, its potential impact on key stakeholders is likely to be as follows:

The Two-Invoice System commenced on a trial basis in 11 pilot provinces and subsequently scaled, reaching full implementation at the end of 2018.



### Manufacturers

- Be more strategic in distributor selection and upgrade their business models to restructure according to the new network.
- Search for appropriate partners, renegotiate pricing and work toward improving overall operational efficiency of the supply chain.
- They would also need to select initial pilot sites in the form of provinces to test new systems and replicate them in other regions.



### Distributors

- Through the policy, distributors can leverage the opportunity to showcase their capabilities in order to establish their space in the market.
- They could use existing competences to expand coverage across geographies and accounts.
- They could also proactively extend to manufacturers to renegotiate their sales contract to further build their sales in market.



### Investors

- With the reduction in overall intermediaries, significant opportunities arise in vertical and horizontal integration.
- This would generate significant investment opportunities as investors would need to concentrate on top manufacturers and dealers holding significant coverage over hospitals in China, enabling them to become potential industry leaders.

51. "The Key to Successfully Selling Medical Devices in China and Japan – Good Distributors", Pacific Bridge Medical, [Link](#)

52. "Best Strategies for Distributor Search in China", MedTech Intelligence, [Link](#)

## Distribution network in India

With nearly 75 percent of medical devices in the Indian market being imported, pressure on the distribution network to be high performing and systematized has intensified. A key factor contributing to the complexity of the Indian market is its heterogeneity and diversity. There are 29 states, each with its own set of health policies and a stark difference in the urban and rural healthcare accessibility.

Indian distribution network is highly fragmented with a number of domestic players operating in the market. However, most of the suppliers currently only operate in core metropolitan areas and tier 1 and 2 cities. The number of distributors with nationwide coverage is low and this has led to companies formulating multiple relationships to establish a pan-India network.

Essentially, medical devices companies, both domestic and international, are largely dependent on importers and distributors for logistics purposes. The supply chain network varies for low and high-value medical devices. Unlike other APAC countries, the role of these distributors in India is mostly limited to logistics, while acting as a facilitator between the manufacturer and hospitals. Distributors usually do not hold the authority over labeling or other authorization processes.

### Procurement of devices

Procurement by public hospitals is largely conducted through government tenders. This also includes public healthcare institutions such as army hospitals and AIIMS (largest group of autonomous government hospitals in India). Private hospitals tend to follow the route of one-on-one deals and request for proposals (RFPs). For small-scale devices such as consumables, hospitals tend to go for one-on-one deals while for large-value devices, hospitals still prefer limited tenders. The role of distributors, however, still is limited to the last-mile delivery and where necessary, installation.<sup>53</sup>

### Transition in the model of distribution

Prior to in 2017, medical devices were mainly unregulated in the country, apart from the 10 devices covered by the Drugs and Cosmetics Act, 1940. For a medical device manufacturer to operate in the market, an import license was required. Post the new rules introduced in 2017, a company that wants to import, manufacture or sell medical devices in India needs to abide by the rules set at a standard of comparable international best practices.

Among the new rules is one that requires medical devices that are imported, sold or distributed in India from 1 January 2022 to have two different types of unique identifiers — **device identifier and production identifier**.<sup>54</sup>

Another major improvement brought about is convenience in the application for a license to distribute devices of any category, which can be submitted on the Ministry of Health and Family Welfare's online portal.

In March 2018, the Department of Pharmaceuticals (DoP) released certain guidelines for implementation of the **Public Procurement Order (PPO)**, for medical devices **covering tenders valued at less than US\$75,000 (INR5 million)**. The guidelines proposed that in order to be eligible for public procurement, medical devices would need to have a minimum local content ranging from 25 percent for instruments and equipment to 50 percent for consumables.<sup>55</sup>

In line with the PPO, preference would be given to local companies provided there is enough capacity and competition in India (at least two local suppliers for each tender). Where a foreign manufacturer is the lowest bidder, domestic firms will be asked to match the lowest bid to supply 50 percent of the contract.<sup>56</sup>

With a heavy dependence on imports, it is imperative for market participants and new entrants to be vigilant of how the import system works in the country. Import of medical devices requires licensee to adhere to stringent regulatory guidelines with respect to registration and licensing of the device.

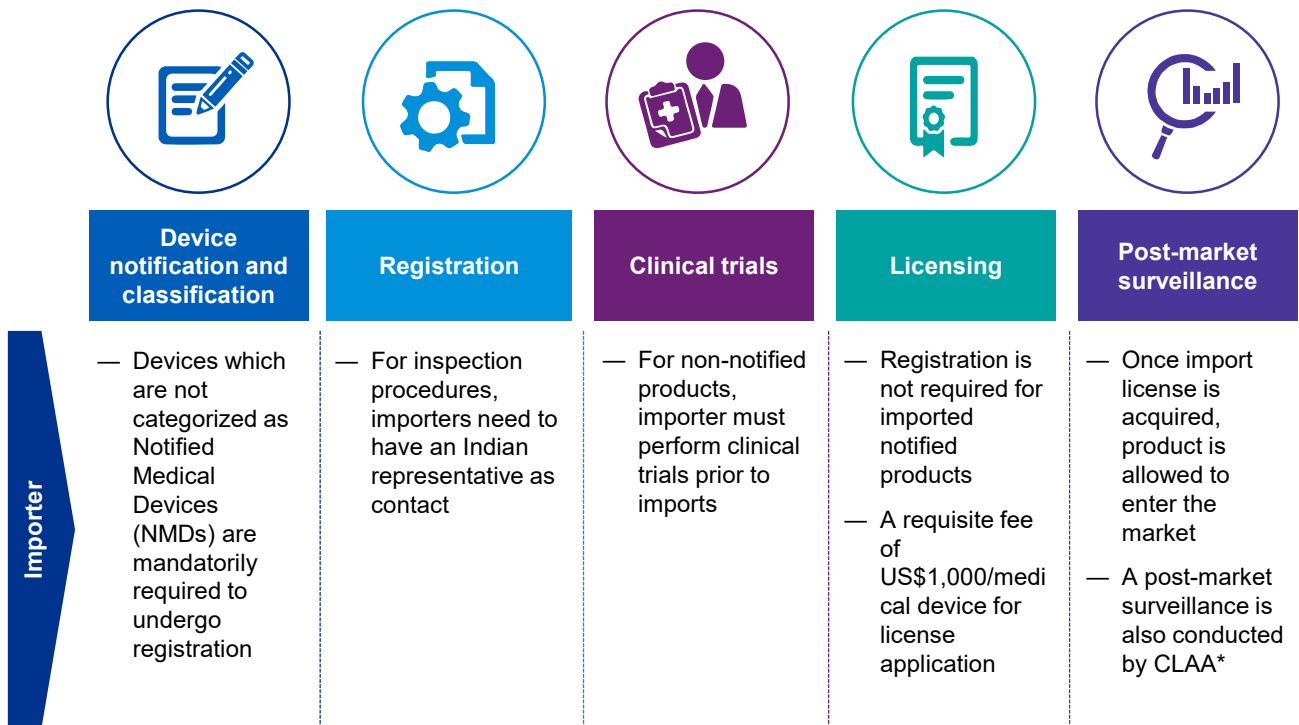


53. "Distribution challenges for medical equipment & devices in India", Value Notes, [Link](#)

54. "Make In India Mittelstand", Make in India.de, [Link](#)

55. "India: India's New Medical Device Regulations", Mondaq, [Link](#)

56. "India's New medical device Regulations", Lexology, [Link](#)



### The long road ahead for Indian distributors<sup>57</sup>

The market ahead for distributors seems quite aggressive. From a stronger regulatory network to opening new channels for sales, the opportunities appear significant. The market is expected to evolve in three key ways:



There is expected to be strong market consolidation within Indian distributors. A system of organized distribution is expected to develop with the aim of large regional distributors acquiring or partnering with small-scale third-party distributors to gain more market in the long run.

Focus on quality will be high in the coming years and there is expected to be improvement in the overall supply chain network of the industry. More credible distributors will be preferred for the government to make the mandate more inclusive and in order to expand the list of medical devices covered under the regulatory system.<sup>58</sup>

In addition, online channels of procurement such as Medikabazaar and Udaan are expected to facilitate direct B2B sales and eliminating multiple middlemen. The Government has also facilitated an online portal for public procurement where hospitals can procure equipment directly from companies, replacing the traditional tender route.

Note: CLAA stands for Central Licensing Approval Authority

57. "Distribution challenges for medical equipment & devices in India", Value Notes, [Link](#)

58. "India's new medical device regulations: 10 things you need to know", Med City News, [Link](#)

## Distribution network in Malaysia

The medical devices industry in Malaysia encapsulates a robust range of equipment including surgical gloves, orthopaedic devices and imaging equipment. Malaysia continues to be one of the leading producer and supplier of catheters and rubber gloves, supplying nearly 80 percent and 60 percent of the global market, respectively.<sup>59</sup>

Global leading medical device companies have their own subsidiaries located in Malaysia, and they tend to outsource warehousing, logistics and billing. Medical device distribution market is close to oligopoly with DKSH, Zuellig and Pharmaniaga who have distribution and marketing functions.<sup>60</sup>

	Medical devices manufacturer-led model	Local agent (distributors)-led model
Supply chain management	Many of the major foreign medical device manufacturers outsource major forwarder for import and customs duties.	Not applicable
Manufacturing labeling	Many of the major foreign medical device manufacturers outsource 3PL (warehousing, labeling and delivery).	For a mid-sized foreign medical device manufacturer that does not have a local subsidiary, the agent performs 3PL in its own warehouse. To public medical institutions, local Bumi agents manage warehousing, labeling and delivery.
Sales order and billing	Order receiving and debt collection business are outsourced to a company different from the 3PL or 4PL for the consignee.	Order receiving and debt collection services are outsourced to another company or in-house. Payment terms from hospitals average 4–6 months for public hospitals and 1–2 months for private hospitals.
Inventory and shipping	While high-end medical device (specially controlled medical device) or new product to be launched, they are direct shipped to hospitals; low-end or medical consumables, they are shipped via dealers to hospitals.	To public medical institutions, local Bumi agents ship the medical devices to hospitals. Majority of medical consumables delivery to public medical institutions, one distributor has signed a 10-year contract with the Federal Government of Malaysia. <sup>61</sup>
Consignment management	Medical device manufacturers manages the consignment for high-end medical device. When in-hospital use is made, hospital places the replenishment order to the manufacturer, and the manufacturer makes a replenishment request to the 3PL of the consignee.	Dealers/agents will typically take charge of consignment management. When in-hospital use is made, hospitals place the replenishment order to the manufacturers, then manufacturers request dealers/agency to ship for replenishment.
Use/return aftercare	Leading manufacturers have in-house Sales & Marketing (S&M) department and provide customer services to the hospitals.	Distributors have S&M department in the company and provide customer services to the hospitals.

59. "Guide on medical device industry in Malaysia", MIDA, [Link](#)

60. Primary data provided by local subject matter professionals in Malaysian medical device industry, interviewed by KPMG, March 2019

61. "Pharmaniaga unit inks 10-year concession agreement with govt", The Edge Markets, [Link](#)

**For companies to distribute in Malaysia, they must acquire a license, while some companies outsource distribution to third parties.**

- Distributors in Malaysia are typically supported by third-party logistics (3PLs) that cover activities such as shipping order, pick up, pack and ship at the warehouse, and deliver the products to the customers
- Companies are now looking into 4PLs that also manage order taking and cash collection services

DKSH deploys its distribution network nation-wide (Malay peninsula and Brunei) having multiple distribution centers (DCs) and sales offices to provide the full fledged distribution services to medical device manufacturer.<sup>62</sup>

Unlike DKSH, Zuellig in Malaysia deploys its regional distribution hubs in Malay peninsula and Brunei respectively to connect with its local DCs where located close to the sales office so as to provide the distribution, sales and product marketing.<sup>63</sup>

Pharmaniaga deploys major four distribution centers in Malay peninsula and Brunei, and the sites of manufacturing through R&D to marketing functions located in near Kuala Lumpur. Sales branch office is located in northern Malay peninsula.<sup>64</sup>



### Consignment management

- High-end products with high cost value are usually distributed through consignments
- The consignment management function within a medical devices company controls the consigned products. For replenishment, the principal requests 3PL/4PL to send a product based on replenishment calculation
- Those consignments are managed manually (i.e. without any automated systems). There are very specific cases where some automation is done

### Role of third- and fourth-party players

Medical devices companies in Malaysia typically conduct demand planning and procurement on their own and do not outsource it to 3PLs. Demand planning is taken care of by the principals and imports are typically handled through major freight forwarder companies.

There are the key specific distributors in the Malaysian medical devices market. These distributors act as 3PLs and 4PLs for companies, managing functions from order collection to packaging to distribution and consignment services.

These logistics partners are typically aligned under two major functions — **sales and marketing, and consignment management.**<sup>65</sup>

Malaysia has evolved as a crucial center for medical devices manufacturing in the APAC with over 200 manufacturers operating in the market. The key enabler for such a thriving market is a well developed logistics and supply chain network.

A major advantage to manufacturers has been the network of integrated logistics that connect the country with the markets across APAC. An important element of this network are the 13 Free Industrial Zones (FIZs). FIZs are export processing zones across the country, developed to facilitate smooth exports, including medical devices. Companies in FIZs are allowed duty free imports of raw materials, components and equipment required in the manufacturing process. Areas where FIZs are not present, companies are allowed to set up Licensed Manufacturing Warehouses (LMWs).<sup>66</sup>



### Sales and marketing (S&M)

- Major medical devices companies have local entities or their own S&M teams to distribute products directly to hospitals
- High-end or new products are generally distributed directly to hospitals (omitting wholesalers)
- Minor medical devices companies that do not have local entities use Authorized Representatives that have S&M functions.
  - For instance, DKSH or Zuellig act as an authorized representative for some of the medical devices companies

62. "DKSH Malaysia Annual Report 2018", DKSH Malaysia, [Link](#)

63. "Zuellig Pharma", EMIS, [Link](#)

64. "Pharmaniaga Logistics & Distribution", Pharmaniaga, [Link](#)

65. Primary data provided by local subject matter professionals in Malaysian medical device industry, interviewed by KPMG, March 2019

66. "Guide on medical device industry in Malaysia", MIDA, [Link](#)

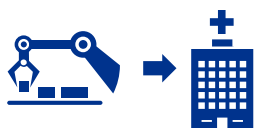
## Distribution network in Thailand

The distribution in Thailand is primarily conducted through two major channels — **government procurement and direct sale to hospitals**. Most agents are based in Bangkok, however, the health services are gradually expanding to more remote areas to encourage distributors to provide nationwide coverage.<sup>67</sup>

### Present scenario<sup>68</sup>

- The regulatory system for public procurement in Thailand was found to have been based on 1990's best practice and did not match up to international standards. Through implementation of a new **Public Procurement Act**, based on international legal models, Thailand aims to enhance the transparency and governance in public procurement
- While the Ministry of Public Health (MoPH) is the **single largest customer of medical equipment**, the central government has started to concentrate more on extending coverage to rural healthcare facilities
- **Local manufacturers, where possible, are given priority over overseas suppliers**

## Models of distribution<sup>69</sup>



### Direct distribution to providers

- This type of distribution includes **public and private sector hospitals and clinics**
- Sale of medical devices to **public sector hospitals is carried out according to government procurement procedures**
- The **Ministry of Finance** has changed the traditional purchasing system, under which:
  - Purchases up to US\$3,127.5 are under **'agreed price'** procedure
  - Between US\$3,127.5 and US\$62,551, the **'price checking'** mechanism was in effect
  - For purchases over US\$62,551, **competitive bidding** was arranged, which has now been replaced with an **e-bidding process**
- Private sector hospitals make purchases according to their own procedures



### Distribution to intermediary companies/representatives

- This type of distribution may be to companies which are part of the same commercial network as the producer or importer
- It also includes general shops/pharmacy/medical stores as a way of reaching target customers in the country
- Players in this group have some degree of healthcare knowledge and are able to leverage a number of distribution channels
- Distributors of medical devices include both wholesale and retail operations. Over 10,000 distributors are active in the sector and nearly all 99 percent are small and medium enterprises (SMEs)



### Distribution to export and import markets

- The majority of goods distributed in this way are single-use devices bound for the main markets of the US, Japan and Germany
- Opportunities for profit-making in the Thai market are somewhat limited due to:
  - The distributors focus on sales to government hospitals, which entails competitive bidding
  - The majority of medical equipment that is imported has a long lifecycle and so new replacements are sourced only infrequently.
  - Producers and importers of raw material face increased costs as a result of currency fluctuations and advent of technology and innovation

67. "Medical devices distribution Thailand", Kha Bangkok, [Link](#)

68. "Thailand medical device distribution", Lexis document, [Link](#)

69. "Local Agent Representation for Medical Products in Thailand", Pacific Bridge Medical, [Link](#)

## Role of third and fourth-party players

Prominent medical devices manufacturers have manufacturing bases in Thailand and tend to outsource warehousing, logistics and billing management. Such activities take place primarily through either a medical devices manufacturer-led model or a local agent-led model:<sup>70</sup>

**For companies to distribute in Thailand, they must acquire a license, while some companies outsource distribution to third parties<sup>70</sup>**

- Distributors in Thailand are typically supported by third-party logistics (3PLs) that cover activities such as shipping order, pick up, pack and ship at the warehouse, and deliver the products to the customers
- Companies are now looking into 4PLs that also manage order taking and cash collection services
- **DKSH and Zuellig** are some of the largest distributors in the market

	Medical devices manufacturer-led model	Local agent (distributors)-led model
Supply chain management	It is required to obtain Certificate for Free Sales when performing import and customs duties	Distributor is responsible for import and customs duties, so it is required to obtain a Certificate for Free Sales
Manufacturing labeling	Many of the major foreign medical device manufacturers outsource 3PL (warehousing, labeling and delivery)	For a mid-sized foreign medical device manufacturer that does not have a local subsidiary, the agent performs 3PL in its own warehouse
Sales order and billing	Order receiving and debt collection business are outsourced to a company different from the 3PL or 4PL for the consignee Payment terms from hospitals average 4–6 months for public hospitals and 1–2 months for private hospitals	Order receiving and debt collection services are outsourced to another company or in-house Payment terms from hospitals average 4–6 months for public hospitals and 1–2 months for private hospitals
Inventory and shipping	Many of the major foreign medical device manufacturers outsource 3PL (warehousing, labeling and delivery)	For mid-sized foreign medical equipment manufacturer that does not have a local corporation, the agent performs 3PL in its own warehouse
Consignment management	Consignment management is conducted by the manufacturer. When in-hospital use is made, the scanned data is sent with the S&M team of the manufacturer and the manufacturer makes a replenishment request to the 3PL of the consignee*	Dealers/agents will typically take charge of consignment management. When in-hospital use is made, the scanned data is sent with the S&M team of the manufacturer and the manufacturer makes a replenishment request to the 3PL of the consignee*
Use/return aftercare	Leading manufacturers have in-house Sales & Marketing (S&M) department and provide customer services to the hospitals	Distributors have S&M department in the company and provide customer services to the hospitals

Note: Small-sized hospital and public hospitals manually place the replenishment order  
70. Primary data provided by local subject matter professionals in Thailand medical device industry, interviewed by KPMG, March 2019



# 3.3 An emerging innovation hotspot for medical devices

## Medical devices companies in APAC are poised to break out of emerging markets and feature on the global stage

In recent history, research and development within medical devices were primarily driven by companies in the US and Europe. While medical technology innovation has been a late bloomer in Asia-Pacific, the region is now witnessing rapid transformation as local companies leverage government preferential policies and collaboration models to foster development.

### R&D in APAC is undergoing significant transformation, primarily being driven by the following three themes:



Public private collaboration models that integrate all stakeholders in the value chain



Government initiatives to bolster indigenous development of medical devices



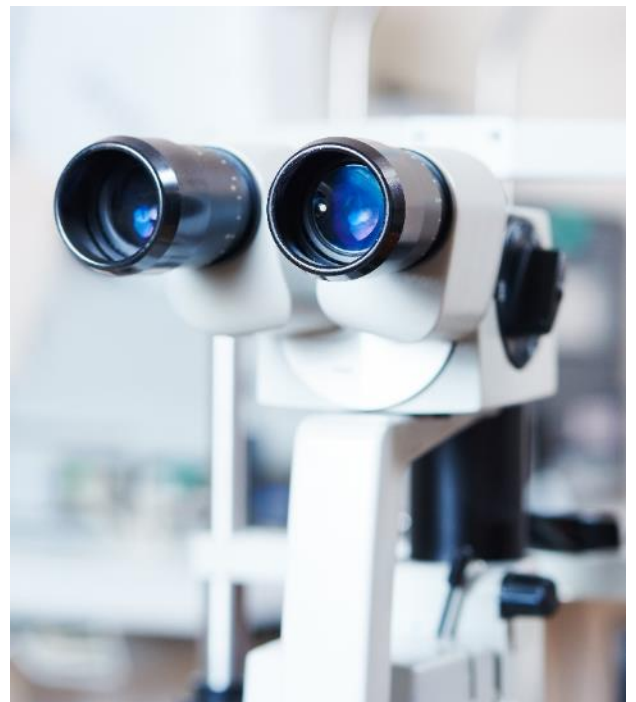
Growing role of multinational R&D centers to develop localized medical devices in APAC

## How are these themes driving research transformation?

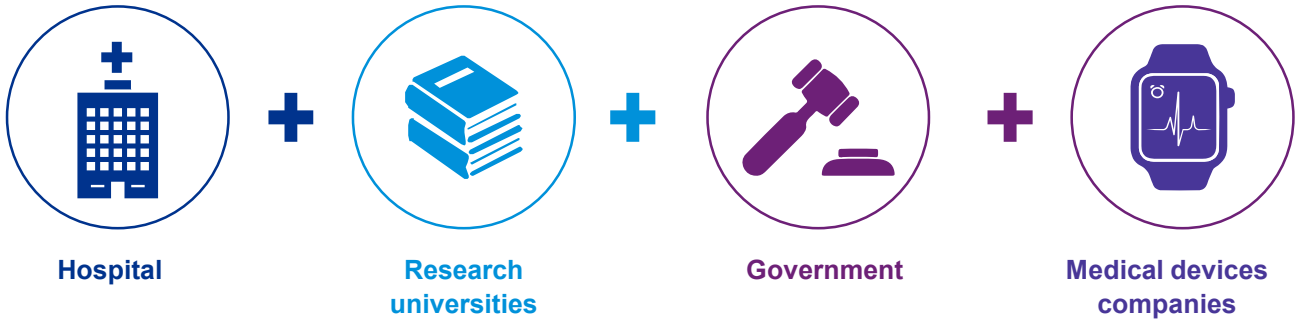
### Public private collaboration models

Historically, the pace of research and development in the region had been slowed down due to segregation in the healthcare sector as well as lack of communication between different players in the field. Medical devices companies, physicians and research universities had been operating in isolation, paying minimal attention toward utilizing each other's discoveries to create new therapies and medical devices.

Nonetheless, over the past decade, collaboration among medical devices companies, government, research universities, and hospitals has broken down traditional silos, resulting in the research and development of new equipment and cutting-edge medical technology.<sup>71</sup>



71. "Accelerating medical device innovation in China", NEJM Catalyst, [Link](#)



**Collaboration models that include all the stakeholders across the value chain have broken traditional R&D silos in medical devices industry**

A leading example of this shared R&D approach is the collaboration model that led to the development of the transcatheter aortic valve replacement (TAVR) device in China in 2012. The collaboration brought together Hangzhou (China)-based company Venus Medtech and Zhejiang Provincial Government to develop a minimally invasive device that could treat patients with aortic stenosis, a degenerative valve disease. Not only did Venus Medtech receive about **US\$2.6 million in research funding from China’s central government**, it was also **granted three years of rent exemption** as well as a **special funding of US\$2.9 million** from Zhejiang Provincial Government.<sup>72</sup>

Similarly, in **Thailand**, the government owned **National Science and Technology Development Agency (NSTDA)** has been working with multiple local medical organizations such as the **Chulalongkorn Hospital** and **Siriraj Hospital**, commission R&D initiatives for medical devices. The collaboration has been focusing primarily on the **application of 3D printing to develop medical implants for skull, jaw and hip prosthetics**. Furthermore, the organizations are also taking initiatives toward the **creating microneedles and medical robotics**.<sup>73</sup>



72. "Accelerating medical device innovation in China", NEJM Catalyst, [Link](#)  
 73. "Medical devices: a new investment opportunity in Thailand", Thai Board of Investment, [Link](#)

## Government initiatives to bolster local market development of medical devices

With an aim to establish APAC at the forefront of medical devices industry, governments across the region are sponsoring numerous initiatives that not only boost local innovation, but also help reduce dependency on imports.

While governments in APAC economies have been making frequent initiatives to enhance local innovation, development of medical devices in the

region is still at a relatively early stage. **Countries in APAC need more investment and opportunities to be able to generate a commercial return on their investment in R&D.** Consequently, a significant portion of APAC's R&D initiatives continue to stem from multinational medical devices companies that started to establish their research centers in the region during the mid-to-late nineties.



Japan's government research agency AMED is executing multiple projects in device development<sup>74</sup>



India's first MedTech institute aims to drive native growth and reduce dependency on imports<sup>75</sup>



Thailand's 4.0 growth model creates an innovation center to boost development of medical devices<sup>76</sup>

- **2015: Government of Japan** founded the **Japan Agency for Medical Research and Development (AMED)**. The agency is overseen by the Office of Healthcare Policy in Japan and **promotes integrated R&D** in medical fields such as drug discovery, medical devices, and regenerative medicines
- Under its **project for medical devices development** (prescribed **budget of about US\$133 million** or JPY14.6 billion), AMED is carrying out multiple projects for the **development of advanced medical devices** such as **flexible endoscopic surgical system, smart treatment room, and cancer diagnostic and treatment navigation systems**

- **2017: To drive indigenous development of medical devices and reduce dependency on imports** (currently 70–90 percent), the **Association of Indian Medical Device Industry** collaborated with the Government to launch India's **first medical technology institute, the 'Kalam Institute of Health Technology'** in Andhra Pradesh
- The institute aims to **conduct focused research on critical components pertaining to medical devices**. It also seeks to undertake research and analysis about the concerns and long-term strategy for Indian MedTech industry

- **2019: Under the new Thailand 4.0 growth model**, the Government of Thailand is seeking to **increase R&D activity in medical devices sector** through the creation of the **Intellectual Property Innovation-Driven Entrepreneurship Center (IP-IDE)**
- The center maintains its own pool of data and patent information that it shares with small and medium sized enterprises (SMEs) developing any kind of new technology. As a result, with the IP-IDE center, the Thai government aims to **encourage Thai medical devices firms to innovate** and expand across both domestic and foreign markets

74. "Development of Medical Devices and Systems for Advanced Medical Devices", Japan Agency for Medical Research and Development, [Link](#)

75. "India's 1st medical tech institute, Kalam Institute of Health Technology at AMTZ gets 100% financial support from DBT", Kalam Institute of Health Technology, [Link](#)

76. "Intellectual property protection a 'key element of Thailand 4.0'", The Nation Thailand, [Link](#)

### Substantial contribution of MNCs in innovating localized medical devices in APAC

With an aim to **support product development in both global and emerging markets**, a number of leading multinational medical devices companies have **established innovation labs and R&D centers in APAC** over the past decade. The companies have primarily focused on countries such as **India and China** with a strong talent base in analytics and software to expand their R&D capabilities in the region.

#### Philips

The company operates a **Healthcare Innovation Center (HIC)** in **Pune, India**. At HIC, teams of R&D, design and software developers collaborate to develop fixed and mobile **diagnostic imaging systems, mobile surgical units, cath lab equipment, and mammography devices**<sup>79</sup>

- Furthermore, with an aim to **reduce risk to life** through **predictive maintenance**, the center has been developing technologies using **big data** to **predict system failures**
- In addition, it also operates an **innovation campus** in **Shanghai (China)** that primarily focuses on **innovating imaging systems and clinical applications, intelligent clinical IT solutions, and patient monitoring systems**<sup>80</sup>

#### GE Healthcare

With the participation of over 5,000 engineers and scientists, **John F. Welch Technology Centre (JFWTC)** is **GE's first and largest R&D center** outside the US, located in Bangalore, India<sup>77</sup>

- **Medical innovations at JFWTC** have helped **enhance one of leading global health technology company's capabilities** to improve access to affordable healthcare **across ASEAN**
- For instance, the center developed a **full-body CT scanner**, that has features similar to a premium CT scanner but is **offered at a fraction of the price**. The scanner, which is estimated to **occupy 50 percent less space and consume 47 percent less power**, is installed in over **150 medical facilities** in key ASEAN markets including **Vietnam, Indonesia, Malaysia, and Philippines**
- Besides, the center also developed a range of **warmers, resuscitation, and phototherapy devices** with an aim to provide affordable maternal and infant care to ASEAN countries witnessing **high infant mortality rates**<sup>78</sup>

### APAC — a leading location for global 'innovation and Centers of Excellence (CoE)'



77. "Research and Development", GE India, [Link](#)

78. "The Cradle of GE's Innovation", Vietnam Investment Review, published on 11 November 2019, [Link](#)

79. "Healthcare Innovation Center", Phillips India, [Link](#)

80. "Phillips Research China", Phillips China, [Link](#)

## Medtronic

The company operates two **R&D centers in India**, located in **Bangalore** and **Hyderabad**

- While the Bangalore facility develops important aspects of Medtronic's **renal care solutions product portfolio**, the facility at Hyderabad provides **engineering services to the company's Minimally Invasive Therapies Group (MITG)** business units
- One of the key devices developed at Medtronic India Development Centre (MIDC) is the portable hemodialysis system that is specifically suited for patients with **end-stage renal disease in emerging economies**<sup>81</sup>
- Besides India, Medtronic has been operating an **R&D center in Shanghai** (China) since 2012 and announced the launch of a **MedTech innovation accelerator center** in the city in 2019. The innovation accelerator center aims to **support innovations in medical applications of AI, surgical robotics, and neuromodulation**<sup>82</sup>

## Johnson & Johnson

In 2018, **J&J announced the opening of a new regional Asia-Pacific headquarters in Singapore**. Located in the country's **Science Park**, the headquarters houses **J&J's first 'design lab' outside the New York City**. The lab aims to **leverage local insights and research to fuel growth of a regional pipeline of products** for its pharmaceutical, medical devices, and consumer businesses. It also targets to **drive collaborations with partners across the entire APAC healthcare ecosystem** including **government bodies, domestic companies, and academic institutions** to innovate **locally relevant products and solutions**.<sup>83</sup>

Besides, the company has been operating its **dedicated APAC innovation center in Shanghai**. It has also commissioned **satellites in Singapore, Australia and Japan** since 2014. Moreover, the center also **operates an office in China's Suzhou BioBay**, an industrial park with nearly **400 companies engaged in drug discovery, biotech, medical devices and nanotech areas**.<sup>84</sup>

## B. Braun

German medical devices manufacturer B. Braun operates a global CoE for Intravenous Access (IA) in Penang Malaysia. The center is dedicated toward conducting R&D as well as manufacturing safety products and systems such as IV catheters (IVC), scalp vein sets (SVS), and hypodermic needles. Besides operating as the Group's CoE for IA, B. Braun's facility in Penang serves as the company's regional headquarters for APAC. The facility houses one of the company's largest production sites with more than 5,500 employees and five manufacturing plants.<sup>85,86</sup>



81. "Research and Development At India Medtronic", Medtronic India, [Link](#)

82. "Medtronic opens R&D center in Shanghai", FierceBiotech, [Link](#)

83. "Johnson & Johnson Opens a New Asia Pacific Headquarters", Johnson & Johnson, [Link](#)

84. "Johnson & Johnson Innovation Launches Asia Pacific Innovation Center and Announces New Alliance", Johnson and Johnson, [Link](#)

85. "B.Braun Medical Industries Sdn. Bhd", B.Braun, [Link](#)

86. "B.Braun Asia Pacific", B.Braun, [Link](#)

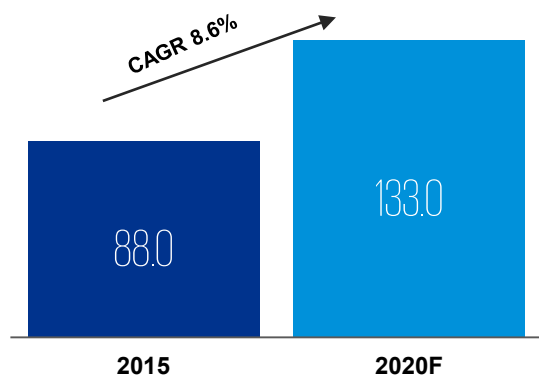
# 4. Key trends in medical devices industry



## APAC medtech market: breaking new ground in healthcare innovation

Driven by demographic trends and rising technology innovation, APAC's medtech industry is forecast to grow in coming years.

**Graph 17. APAC medtech market (US\$ billion), 2015–20F<sup>87</sup>**



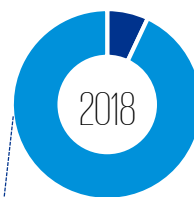
Key drivers attributable to this growth include:

- 1. Growing appetite of multinational players to invest in medtech:** Leading global medtech companies such as Medtronic and AB Sciex have set up their manufacturing plants and R&D units across APAC. They are also engaging in partnerships with local players. For instance, a Switzerland-based pharma company partnered with one of India's largest life sciences company to extend market penetration of its blood glucose monitor. With these initiatives, the companies aim to leverage APAC's rapidly growing medical devices sector to achieve their expansion plans
- 2. Growth of domestic medtech companies and PE investment:** Local medtech players in APAC are making advanced innovations and are increasingly being supported through investments from private equity firms that have identified the region as an appealing sector for growth. During 2011–15, a total of US\$23 billion was invested by PE firms in APAC Medtech sector<sup>88</sup>
- 3. Government initiatives supporting growth of medtech firms:** Governments across APAC have launched policies that support local innovation in medtech. For instance, the Thailand Board of Investment has announced an eight-year corporate tax exemption for manufacturers developing high-technology medical devices

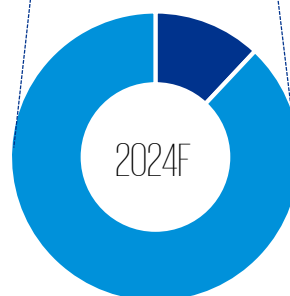
As a result, medtech firms in APAC are increasingly adopting digital solutions such as cloud computing, internet of medical things (IoMT), and big data analytics to drive growth of high-tech medical devices in the region. For instance, APAC is estimated to emerge as the fastest growing market in connected medical devices segment by 2024<sup>89</sup>

**Graph 18. APAC share in global connected medical devices market (%), 2018–24F<sup>89</sup>**

7.0% = US\$1.0 billion



CAGR 24.5%  
(2018–24)



12.0% = US\$4.0 billion

■ APAC ■ Global

- Government initiatives toward digital adoption, and growing demand for smart hospitals will stimulate growth of connected devices in the region
- Furthermore, Japan and China are projected to represent the greatest share, capturing two-thirds of the total market

87. "Medtech Industry In APAC", APACMED, [Link](#)

88. "Medtech in Asia Pacific", Merger Market, [Link](#)

89. "2019 Healthcare predictions unleashed", APACMED, [Link](#)

Increased adoption of complementary technologies such as cloud computing, IoMT, and big data by healthcare institutions in APAC is driving medical device companies to align their strategies towards digital solutions<sup>89</sup>



### Cloud computing

In order to explore innovative solutions for patient centric care, over 90 percent of the hospitals across APAC are estimated to invest about US\$400 million in cloud technologies by 2024



### Internet of medical things (IoMT)

Overall market for IoMT in APAC is estimated to reach US\$10.9 billion by 2024, growing at a CAGR of 30.3 percent during 2018–24.



### Big data analytics

Over 52 percent of the hospitals in APAC are estimated to invest about US\$2.5 billion in order to explore the use of big data analytics



89. "2019 Healthcare predictions unleashed", APACMED, [Link](#)



## Growing shift toward digitalized distribution and route optimization models

Unlike pharmaceutical businesses that appear to have a mature distribution model in place, the medical devices segment is still in the early stages of implementing a model that uses technology and route optimization techniques. In APAC, the level of maturity for distribution model for medical devices varies from country to country. While use of electronic procurement systems appears to have penetrated the market significantly, use of virtual marketing and training as well as payments through Equated Monthly Installments (EMIs) and renewals appears to be at a nascent stage.

### Technology adoption across medical device supply chain in APAC is primarily in the form online procurement systems and e-commerce distribution<sup>90</sup>

- Despite the use of e-commerce channels, standard order to remittance (OTR) time for a medical device is around 30 percent lesser in China and Japan, when compared to India, and is attributable to digital transactions for payments and licenses between different stakeholders across the value chain
- Furthermore, in addition to digital payments and licenses procurement, virtual marketing and 3D product experience are also gaining increased popularity across the medical devices distribution system in the region
- Distributors and ‘original equipment manufacturers’ are currently in initial stages of partnering with large hospital groups to expand this model of selling and distribution. Going forward, this model is projected to increasingly benefit the remote hospital segment in the region

- Majority of the hospitals in China procure large medical equipment through an open bidding process which is normally conducted through centralized online purchasing agents. In addition, e-commerce for medical devices has been expanding in the country with low and mid-end domestic medical devices being main products sold online
- For instance, Chinese e-Commerce company Alibaba.com directly connects manufacturers in China to buyers across the world and provides manufacturer details such as production capacity, trade capacity, and quality management process on their portal



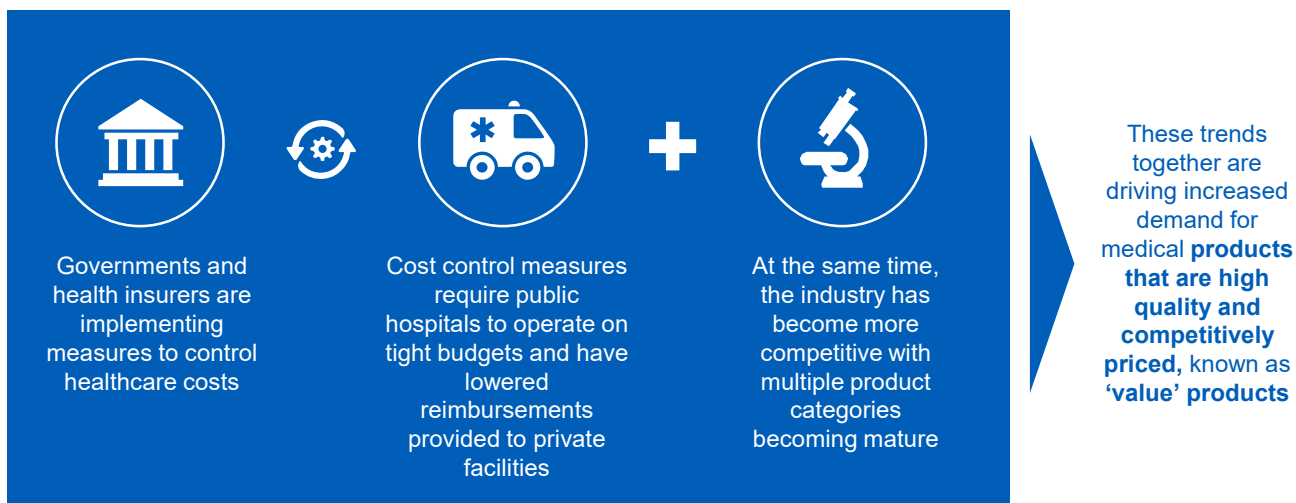
- Numerous B2B online medical equipment suppliers are currently operating in India with the Mumbai based Medicabazaar supplying medical equipment to over 20,000 hospitals and clinics across 23 cities across the country. Furthermore, the company plans to continue expanding and is in talks with venture capital investors from Japan, Belgium, and Germany to raise over US\$112 million
- It aims to use the funds to upgrade technology and expand to tier 3 and tier 4 cities in India. Besides India and China, direct online medical suppliers have also been operating at a large scale across Japan, Australia, Thailand, Malaysia



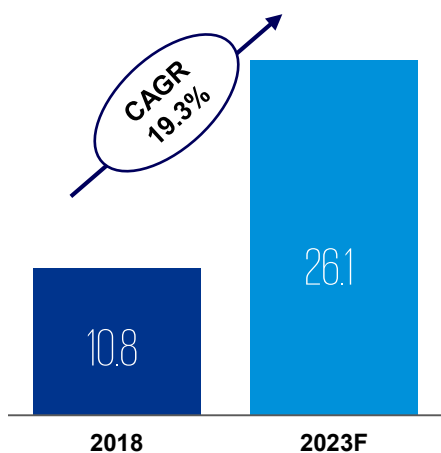
90. "The Medical Devices Market in China", Flanders, [Link](#); "Medikabazaar in talks to raise \$28 million from Japan's Mitsui and others", Live Mint, [Link](#); 2019 Healthcare predictions unleashed", APACMED, [Link](#)

Government measures to control healthcare costs as well as growing middle classes are driving a transformation in the purchasing process of medical devices in APAC markets.

**The transformation has significantly modified the way medical devices are bought and valued, thereby resulting in the growth of the so-called ‘value’ product segment in the region.**

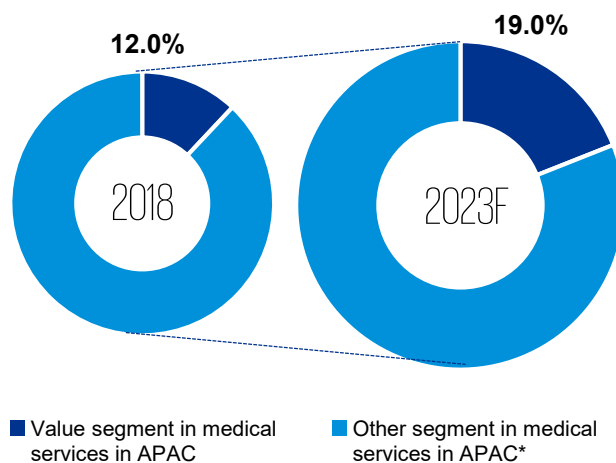


**Graph 19. Growth of ‘value’ product market in APAC (US\$ billion), 2018–23F**



- In the coming years, market for value products is estimated to occupy a significant share in total medical devices purchases in APAC
- This is primarily attributable to growth in tier 1, tier 2, and public hospitals in emerging APAC markets

**Graph 20. Revenue share of ‘value’ products in total: APAC medical devices market (%), 2018–23F<sup>91</sup>**



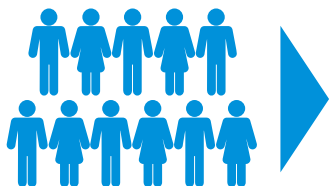
- Revenue share of value segment products out of the total APAC medical devices market is estimated to increase from 12 percent in 2018 to 19 percent in 2023

Note: Value for 100% total market was unable through the sources referred; \*Other segments in medical devices sector include three categories: premium differentiated products (innovative products with proven clinical benefits that demand a high price), undifferentiated products (products that are sometimes innovative but do not have proven clinical benefits), and basic products (products that mostly compete on price and are used to provide a basic and undifferentiated service), MDDI Online, [Link](#) 91. “2019 Healthcare predictions unleashed”, APACMED, [Link](#)

## Aging Asia triggering a rise in assistive medical robotics

With demographic clock ticking in APAC, the region is currently at the forefront of the global phenomenon of population aging. By 2050, one in four people in Asia-Pacific are estimated to be over 60 years old.

### The growing needs of aging population are key drivers for assistive technology



In 2016, nearly 12.4 percent of the population in the region was 60 years or older in age, and this is forecasted to increase to more than 25 percent (1.3 billion) people by 2050.<sup>92</sup>

- While Japan's aging population is leading the phenomenon, other Asian economies including China, Malaysia, Thailand, and Australia are in nascent stages of a similar course
- Consequently, rapidly aging societies in these nations, specifically Japan, are driving the growth of medical assistive robotics for elderly care<sup>93</sup>



Key assistive robots operating in the Japanese market include:

- A leading health-tech company in Japan developed a medical robot that assists medical care workers in moving older patients from bed to wheelchair
- Another health-tech company developed a wearable exoskeleton muscle suit that is designed to amplify the caregiver's strength while assisting the elderly
- PARO, an interactive therapeutic robot that is designed to stimulate patients with cognition disorders such as Dementia and Alzheimer's<sup>94</sup>



- In Thailand, the Thailand Board of Investment (BOI) has offered a wide range of investment promotion incentives related to the manufacture of medical robotics
- Currently, the Dinsow mini, an elderly care robot manufactured by Thai company CT Asia Robotics which is equipped with AI technology, has been assisting the elderly with Alzheimer's in the country<sup>95</sup>



- Medical care facilities across Australia are also using human-like robots including ZORA that is designed to assist the elderly with activities such as leading a physical therapy class, reading out TV programs, weather forecasts, and local news<sup>96</sup>

92. "Ageing in the Asian and Pacific region: An Overview", United Nations ESCAP, [Link](#)

93. "Ageing Asia spurs rise in assistive robots, tele-healthcare", Medium, [Link](#)

94. "How the Medical Industry is Improving Life for Japan's Aging Population", Harvard Business Review, [Link](#)

95. "A Thai-made robot that takes care of those with Alzheimer's", The Nation Thailand, [Link](#)

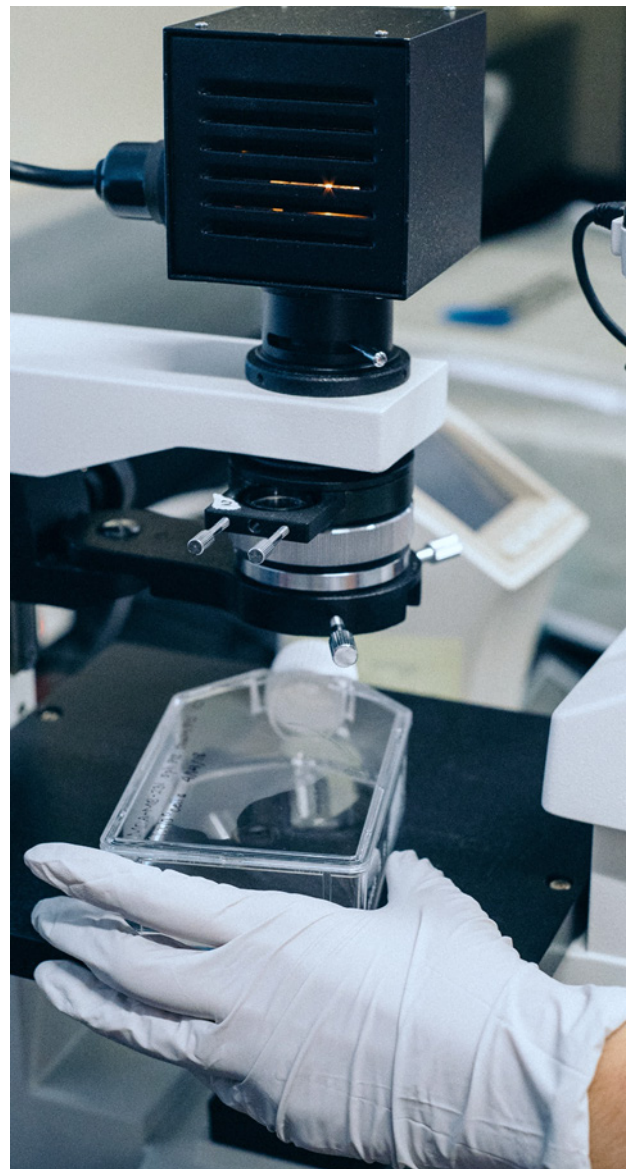
96. "This human-like robot is lending a helping hand in aged care homes", Create Digital, [Link](#)

## Advanced medical devices fueling growth of medical tourism across APAC

Cost-effective treatments and availability of comprehensive medical care under one roof have transformed Asian countries, especially India, Thailand, and Singapore, into ideal locations for medical tourism <sup>97, 98</sup>

Over recent years, an increased number of patients from both developed and emerging economies have been traveling to these countries for medical treatments that combine a holiday along with an executive check-up or surgery

- In addition to the presence of professional skill that is similar to their **western counterparts**, a key factor driving medical tourism across India, Thailand, and Singapore is availability of **modern diagnostic and therapeutic equipment** that adheres to international quality standards. Consequently, a leading factor driving growth of the medical tourism industry in APAC is continuous growth of its medical devices sector. Key elements within the sector that are influencing growth of medical tourism in the region comprise the following:
  - Hospitals in these nations have made notable progress in the fields of **heart surgery, minimally invasive surgery and robotic endoscopic coronary bypass surgery, to name a few**. This is primarily due to advancement in **invasive and non-invasive medical devices** in the region that are estimated to have grown tremendously in these segments
  - Significant progress has also been made in the development of catheterization laboratories across hospitals and clinics in APAC. This is primarily due to advancement in **high resolution imaging equipment, multiple view high frame rate systems, digital enhancing systems**, and 3D imaging systems that have made diagnostic imaging procedures performed in catheterization laboratories more sophisticated<sup>97</sup>



97. "Medical Tourism", Business-in-Asia, [Link](#)

98. "Asia-Pacific to Gain Prominence in Medical Tourism Market at Fastest CAGR of 15.5%", PR Newswire, [Link](#)

# 5. Regulatory landscape



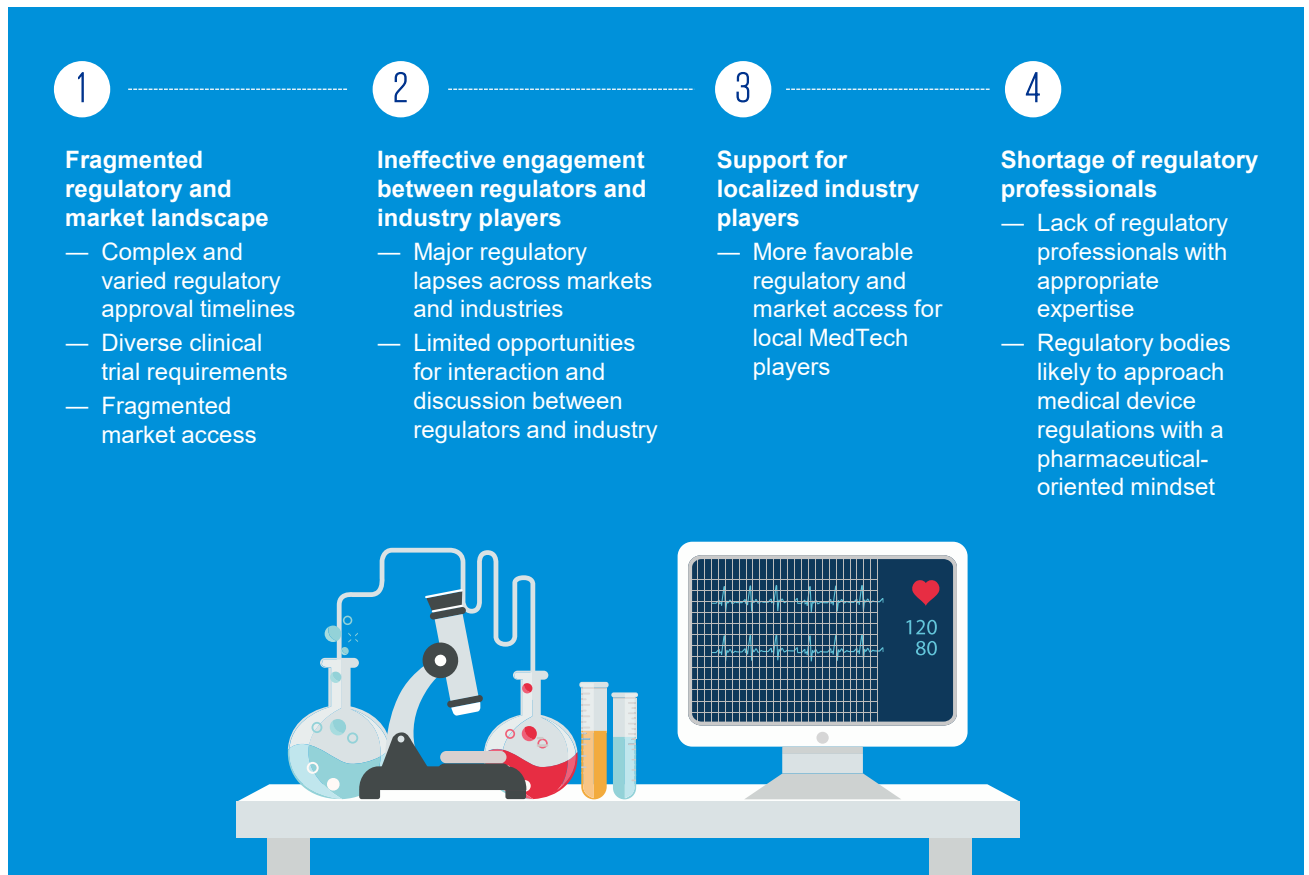
**The most crucial stage for a medical devices company to launch a new product is receiving regulatory approval. In cases, the process can be tedious and time consuming, thereby increasing the effort and time needed to launch the new device. While APAC poses tremendous potential and a vast market for medical devices companies, the channel to launch a new product in the region can be extremely complicated depending on geography.**

As the medical device market expands globally, there is near-universal demand for safe, high-quality products as well as global push for harmonization of device regulations. Nevertheless, the regulatory landscape in the APAC region continues to vary and fluctuate from having little or no structure to highly evolved regulatory systems as seen in Japan and Australia. The key attributes of the regulatory landscape in the medical devices sector in APAC can be summarized as below:

In 2016, the Asia Pacific Medical Technology Association (APACMed) conducted a survey receiving inputs from 130 senior executives from 18 multinational medical devices companies with an active presence in the APAC region. The findings of the survey indicated that regulatory and related issues were the top concern for medical devices manufacturers operating in the region. While intensified regulatory challenges were noted by over 90 percent of the respondents, only 35 percent believed that they were equipped with required capabilities to address the issues.<sup>99</sup>

Consequently, **regulatory issues continue to be among the leading hurdles** and key areas of focus for medical devices sector in the APAC region. **Regulations continue to vary across the region and are constantly evolving.** This makes it critical for medical devices manufacturers to stay well informed of any changes in the region and consider their APAC regulatory strategies early on in the product development lifecycle.<sup>100</sup>

If we account for the pace of regulatory change, the stringency of laws and the degree of coverage of regulations, the landscape of each country could be classified into **highly evolved, moderately evolved and at nascent stage.**



99. "Building Regulatory Professional Capacity for Medical Devices in Asia Pacific", APACMed, [Link](#)

100. "4 APAC Countries With Shifting Medical Device Regulations: What You Need to Know", Premier Research, [Link](#)

## Highly evolved regulatory systems for medical devices in Japan

### Medical devices regulatory framework in Japan

- Japan, which is often touted as one of the most established medical devices markets globally, is also known to operate a highly evolved and comprehensive regulatory system for medical devices. To sell a medical device in Japan, the manufacturer is required to be compliant with the Pharmaceuticals and Medical Devices (PMD) Act, issued by the Ministry of Health, Labour, and Welfare (MHLW). Compliance to PMD Act is assessed by either the Pharmaceuticals and Medical Devices Agency (PMDA) or designated Registered Certification Bodies (RCBs)

### Salient features of medical devices regulations in Japan<sup>101, 102</sup>

Classification and product registration: Japan uses the Japan Medical Device Nomenclature (JMDN) system, under which generic names and codes are established in accordance with the Global Medical Device Nomenclature (GMDN). These generic names are further classified under one of the four medical device classes, from I to IV

The Japanese regulatory system follows a risk-based classification of devices that aligns with the guidelines established by the International Medical Device Regulators Forum (IMDRF)

- **Class I general medical devices:** Includes devices that pose low risk to human body such as surgical instruments (scalpels and tweezers), and X-ray films
  - Requires manufacturers to file a pre-market submission (also known as “Todokede”) through a Marketing Authorization Holder (MAH); this results in a marketing notification and no review or assessment is conducted by the PMDA
- **Class II and limited Class III controlled medical devices:** Includes devices that pose low risk to human body such as MRI scanners, dialyzers and mechanical ventilators
  - Requires manufacturers to file for pre-market certification (also known as “Ninsho”) through a MAH. Further, for devices that have established certification standards by MHLW, the review can be conducted by RCBs. In case certification standards do not exist, the device needs to be submitted to PMDA for MHLW approval
- **Class III and Class IV specially controlled medical devices:** Includes devices that pose medium or high risk to human body or are highly invasive such as artificial bones, artificial heart valves, and stents
  - Requires manufacturers to file for pre-market approval (also known as “Shonin”) through their MAH with the PMDA

Foreign manufacturer registration (FMR): FMR is a crucial step for manufacturers producing their devices overseas but plan to market them in Japan

This process is separate from product registration and is mandatory for a foreign manufacturer to undergo

Further, an FMR certificate is valid for a period of five years. In order to renew certification, the manufacturer must submit a renewal application approximately five months before the expiration date

Additionally, the FMR application should be submitted by the Designated Marketing Authorization Holder (D-MAH) or the Marketing Authorization Holder (MAH)

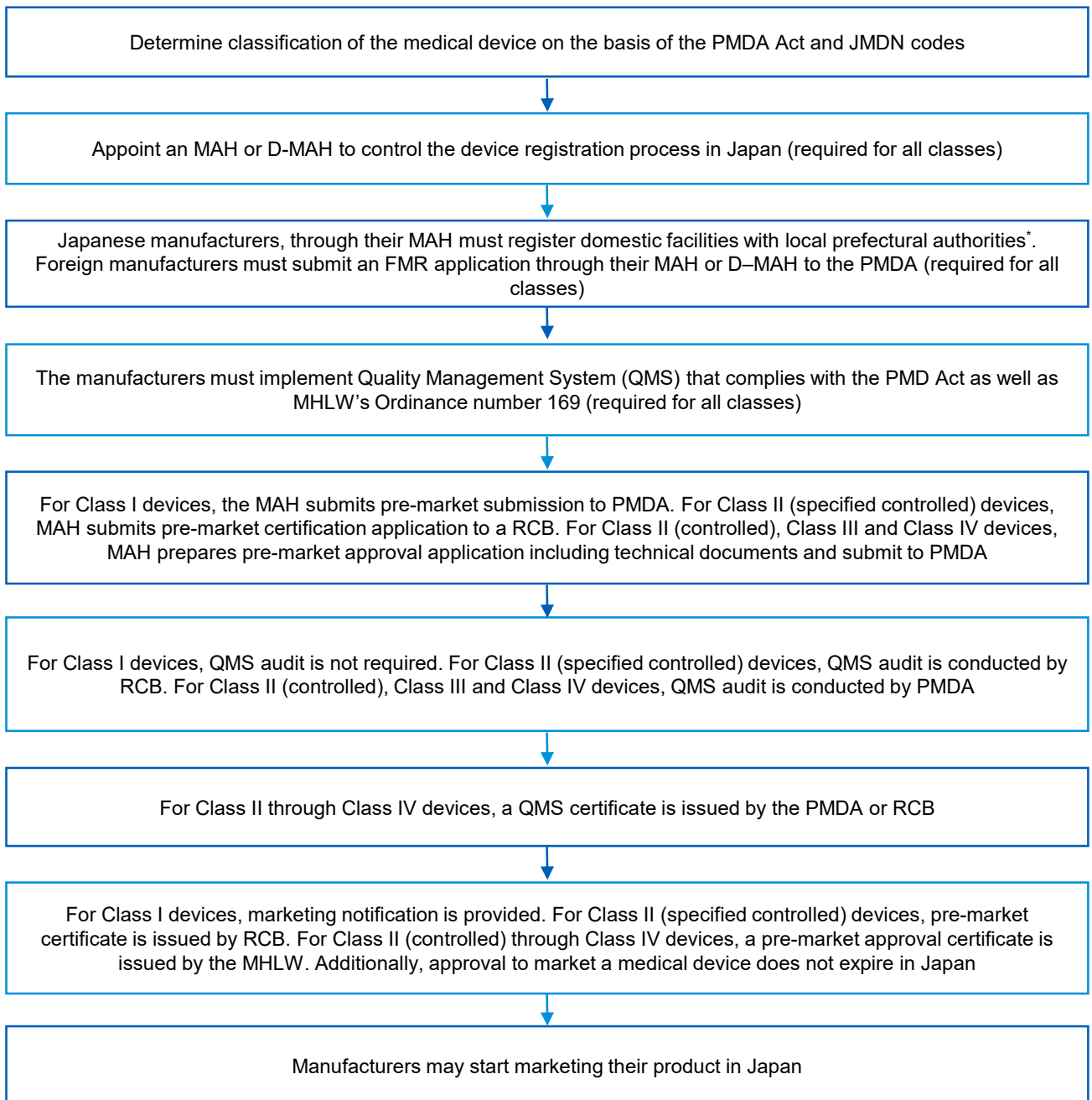
Prior to applying for an FMR certificate, the device manufacturer must also submit a Business Number Registration Form in order to obtain a business number for each manufacturing facility

101. “Comparative study on current regulation of medical devices in Japan and Russia”, Academia, [Link](#)

102. “An overview of medical device regulations in Japan”, RegDesk, [Link](#)

## Highly evolved regulatory systems for medical devices in Japan<sup>103</sup>

The pre-market approval process devised by the PMDA in Japan consists of the following systemic series of steps:



Note: \* Prefectural authorities in Japan are public authorities that are responsible for regional administration  
103. "Japan Regulatory Approval Process for Medical Devices", Emergo, [Link](#)



## Highly evolved regulatory systems for medical devices in Japan

### Key recent developments to the regulations in Japan:

- PMD Act now allows specified medical devices in Class II as well as some Class III to qualify for the designated third-party certification, making the process easier for foreign manufacturers
- A Marketing Authorization Holder (MAH) has been required to submit quality system conformity assessments on a product to get the Quality Management Systems (QMS) certificate since 2014
- However, now PMDA accepts audit report to reduce the required workload for QMS documentation when Medical Device Single Audit Program (MDSAP) participating member countries performed QMS compliance inspection for the medical device <sup>104</sup>



104. "Trial acceptance of MDSAP audit reports in Japan", PMDA, [Link](#)

## Highly evolved regulatory systems for medical devices in Australia

### Medical devices regulatory framework in Australia

Therapeutic Goods Administration (TGA), which is part of the Australian Government Department of Health and Ageing, is responsible for regulating medicines and medical devices in the country. The Australian Register for Therapeutic Goods (ARTG) is the reference database of the TGA and provides information on the therapeutic goods that can be supplied in Australia.

#### Salient features of medical devices regulations in Australia<sup>105</sup>

**Classification of medical devices:** TGA follows the international classification process for medical devices, categorizing them into five classes:

- Class I (low risk devices such as elastic bandages and cervical collars)
- Class IIa (low to moderate risk devices such as x-ray films and contact lenses)
- Class IIb (moderate to high risk devices such as blood bags and dressings for severe wounds)
- Class III (high risk devices such as coronary artery probes and devices that contain medicines such as dressings with an anti-microbial agent).
- Active Implantable Medical Device (high risk devices such as pacemakers and cochlear implants)

**Lifecycle approach to regulation:** The TGA follows a lifecycle approach to regulate medical devices. This implies that for medical devices in lower risk categories, a greater emphasis on regulation is laid after inclusion on the ARTG. Conversely, for higher risk categories, more extensive regulation is executed prior to inclusion on ARTG

**Essential Principles and Standards:** TGA's Essential Principles set out the requirements of medical devices in terms of safety, performance, benefits and risks and they have to be applied to all medical devices. In addition, medical device manufacturer may choose to use the relevant regulatory standard which is not mandatory to demonstrate compliance with the Essential Principles

**Conformity Assessment:** Conformity assessment is the systematic and ongoing examination of evidence and procedures to ensure that a medical device complies with the Essential Principles defined in the Australian Regulatory Guideline for medical devices. The certificate of conformity assessment is to be issued by TGA or European Union Notified Body. TGA has been a participating member of Medical Device Single Audit Program (MDSAP) since 2012 so that TGA also accept certificate issued by MDSAP

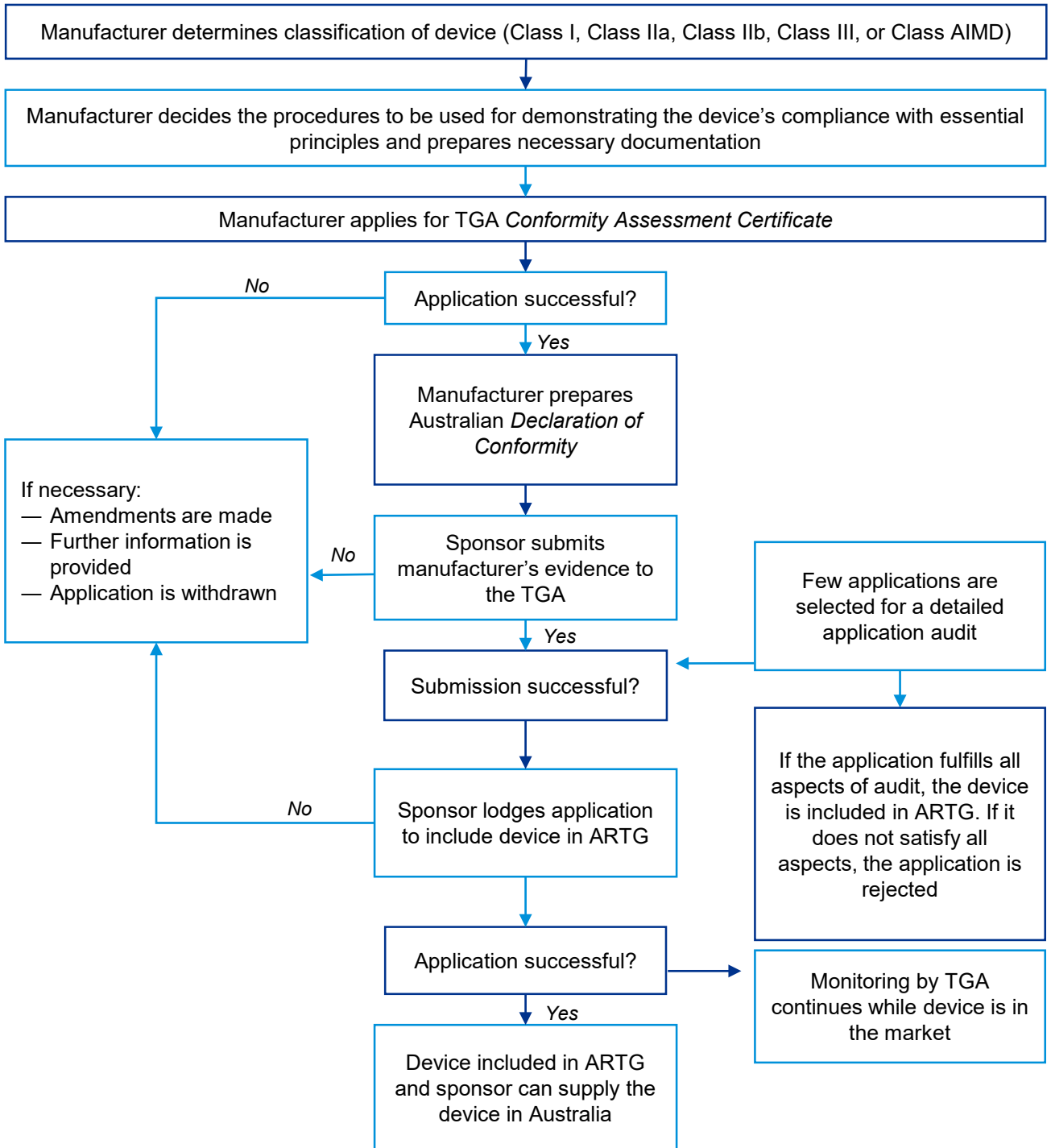
**Role of 'Sponsor':** Similar to government bodies in other APAC countries, TGA requires the manufacturer, distributor, or importer, if the company doesn't have local subsidiary in Australia, to appoint an Australian sponsor who is responsible to act as a liaison between the TGA and the device company

**Process to supply medical devices:** Supply process varies depending on the device classification and the location of manufacturing site but the sponsor is further responsible for managing the entire approval process, gathering the information from manufacturers, evidence for conformity assessment, inclusion of device in ARTG, and submit the samples to TGA upon request

105. "Australian regulatory guidelines for medical devices", Therapeutic Goods Administration, Department of Health, Australian Government, [Link](#)

## Highly evolved regulatory systems for medical devices in Australia

Process to supply medical devices in Australia consists of the following systemic series of steps:<sup>106</sup>



106. "Australian regulatory guidelines for medical devices", Therapeutic Goods Administration, Department of Health, Australian Government, [Link](#)

## Moderately evolved regulatory systems for medical devices in China

### Medical devices regulatory framework in China

In China, the National Medical Products Administration (NMPA), formerly known as the China Food and Drug Administration, is the institution responsible for regulating medical devices in the country. NMPA is an administrative agency of China's Central Government and operates under the jurisdiction of the State Administration for management and supervision of drugs, cosmetics and medical devices.

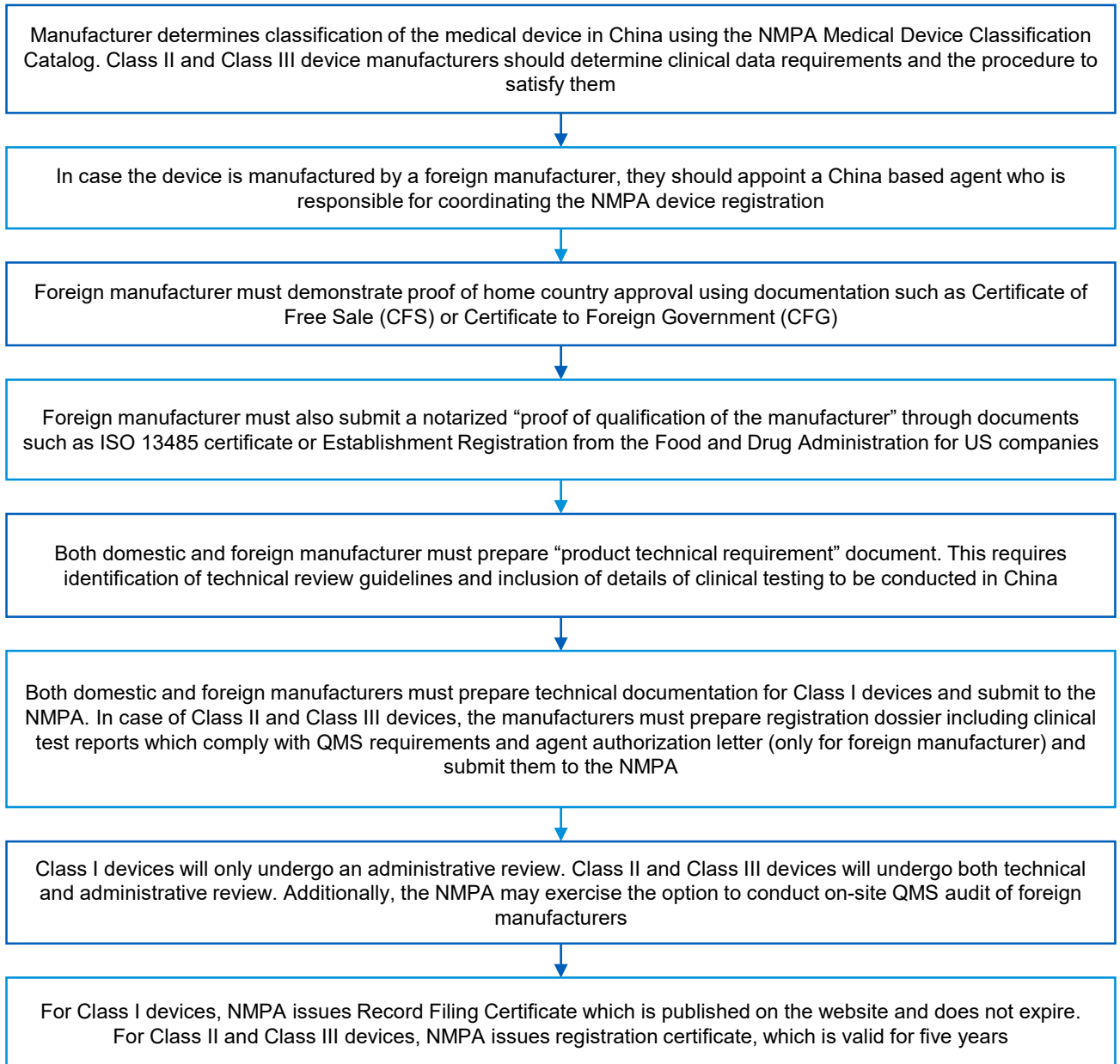
#### Salient features of medical devices regulations in China<sup>107</sup>

- **Classification of medical devices:** NMPA classifies medical devices into three classes depending on their degree of risk. Consequently, the NMPA describes the three classes as follows:
  - **Class I** includes medical devices for which user safety and effectiveness of the device can be conducted by routine administration
  - **Class II** includes medical devices for which safety and effectiveness is ensured through further control along with routine administration
  - **Class III** includes medical devices that are implanted into the patient's body and pose a threat to the patient's health
- **Registration validation period:** medical devices registration validity in China has been extended from four to five years now. Further, if the manufacturer wants to renew the device's registration, a renew application should be submitted to the same department that received the original application, six months prior to the expiration date
- **Requirements from foreign medical device manufacturers:** to register a device that is not manufactured in China, it is required to provide device samples to the NMPA for testing
  - In case of Class II and III devices, the company is also required to provide relevant documents indicating the approval of the device in its country of origin. These include documents such as CE Mark, 510(k) letter and ISO 13485 certification
  - The company may also be asked to provide supportive clinical data along with the application. In addition, they are obligated to provide all product information on packaging and labeling in simplified Chinese
  - In addition, foreign manufactures need to hire a China-based agent who is responsible for representing their interests in China. Consequently, the designated agents are responsible for providing technical and maintenance support for the device, assist with device recall if required, oversee the registration process as well as provide support in case of an adverse event or device malfunction
  - Furthermore, manufacturers are obligated to provide personal information of designated agents in the registration **application to the NMPA**
- **Recent regulation changes:** In 2018, the NMPA published a draft amendment to its medical devices regulations introducing significant changes to requirements
  - The amendment introduced a provision that requires all medical devices to have a unique identification number. With a Unique Device Identification (UDI), NMPA aims to improve the tracking of devices by maintaining a UDI database that stores information such as production and expiry dates
  - Further, all high-risk devices will be subject to clinical evaluation, unless a device has a proven record of safety. Moreover, in case of foreign manufacturers, it is highly likely that clinical data from trials conducted outside of China will be subject to review
  - The amendment indicates prioritization of innovative medical devices. For instance, it allows foreign manufactures to import innovative devices into China without having to provide entry approval certificates from the country of origin

107. "An Overview of Medical Device Regulations in China", Regdesk, [Link](#)

## Moderately evolved regulatory systems for medical devices in China

The pre-market approval process devised by the NMPA consists of the following systemic series of steps:<sup>108,109</sup>



108. "China NMPA Regulatory Approval Process for Medical Devices", Emergo, [Link](#)

109. "Provisions for medical device registration", NMPA, [Link](#)

## Moderately evolved regulatory systems for medical devices in Malaysia

### Medical devices regulatory framework in Malaysia

Medical Device Authority (MDA) under the Ministry of Health in Malaysia is the key regulatory body responsible for the regulation of medical devices in the Malaysian market.

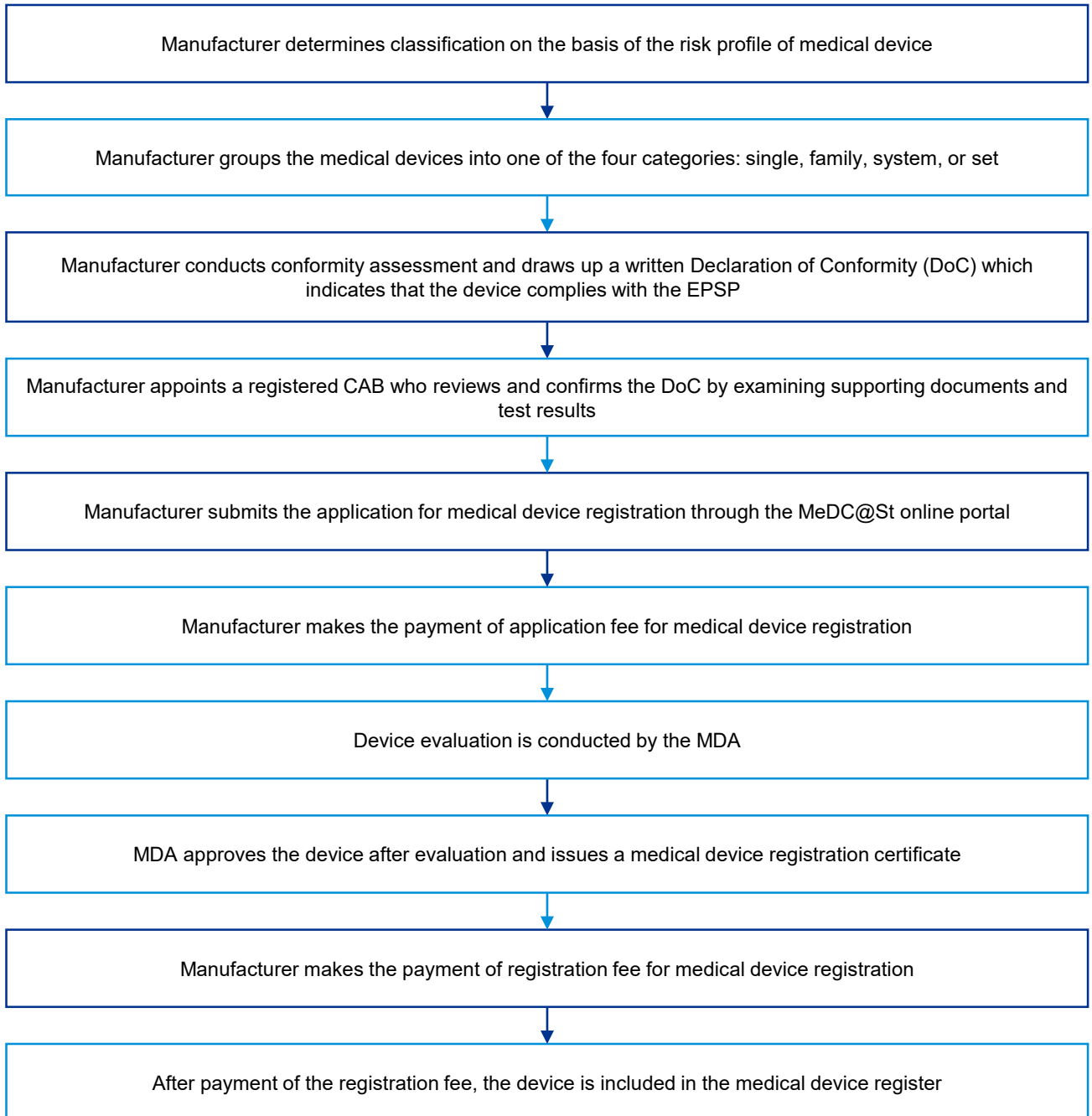
#### Salient features of medical devices regulations in Malaysia<sup>110</sup>

- **Classification of medical devices:** MDA follows the international guidelines for classification of devices. As a result, all medical devices in Malaysia are divided into four categories: Classes A, B, C, and D based on the level of risk associated with the device
  - **Class A** includes low risk devices such as simple surgical instruments and tongue depressors
  - **Class B** includes low to moderate risk devices such as suction equipment and x-ray films
  - **Class C** includes high to moderate risk devices such as lung ventilator and orthopedic implants
  - **Class D** includes high risk devices such as pacemakers and implantable defibrillators
- **Grouping for general medical devices:** In addition to risk based classification, general medical devices are also grouped into one of the four categories including: single, family, system, or set. In order for grouping to apply, the devices must hold the same proprietary and manufacturer name as well as offer one common purpose
- **Role of Local Authorized Representative:** A manufacturer, distributor, or importer of devices in Malaysia is required to **appoint a local authorized representative (LAR)** and ensure that the devices conform to Essential Principles of Safety & Performance (EPSP)
- **Conformity Assessment:** The manufacturer is obligated to undertake systematic examination and determine that a medical device is safe and conforms to the Essential Principles of Safety and Performance for Medical Devices (EPSP). Further, a medical device should undergo conformity assessment by a registered Conformity Assessment Body (CAB) prior to registration. **While Class A devices are exempt from review by the CAB, special cases may be audited. Devices falling under Class B, C or D are required to be assessed by an authorized CAB** to ensure that relevant technical regulations and standards are fulfilled
- **Process to supply medical devices:** A complete application process should be executed on the online portal MeDC@St system. All actions, including submission of general information, declaration of conformity (DoC) and submission of certificate indicating compliance to QMS, are carried out on the portal. MDA verifies classification of the device and upon approval issues a certificate and registration number to the manufacturer

110. "General Medical Device", Medical Device Authority, Ministry of Health Malaysia, [Link](#)

## Moderately evolved regulatory systems for medical devices in Malaysia

The pre-market approval process devised by the MDA consists of the following systemic series of steps:<sup>111</sup>



111. "General Medical Device", Medical Device Authority, Ministry of Health Malaysia, [Link](#)

## Moderately evolved regulatory systems for medical devices in Thailand

### Medical devices regulatory framework in Thailand

The Medical Devices Control Division under the Thailand Food and Drug Administration (Thai FDA) is the regulatory authority that controls all medical device related activity in Thailand.

#### Salient features of medical devices regulation in Thailand<sup>112</sup>

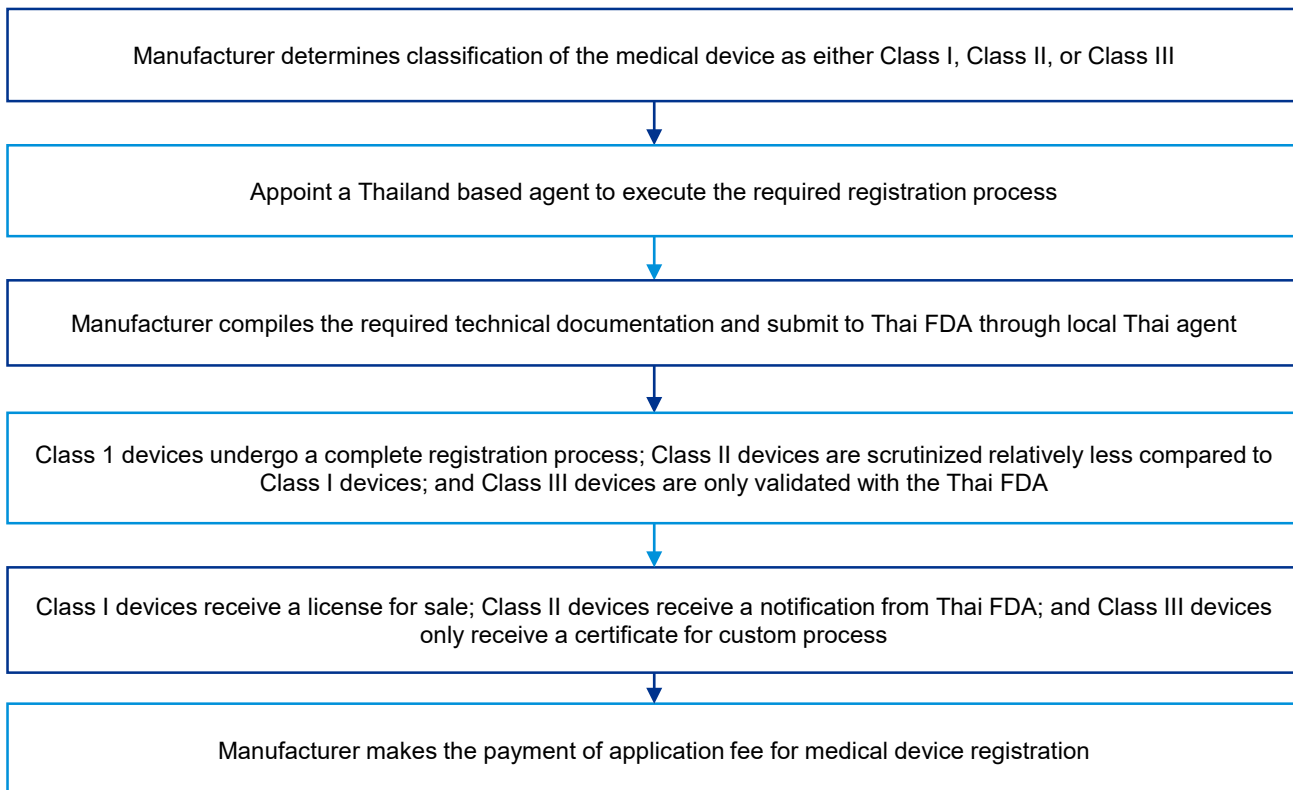
- **Classification of medical devices:** Thailand follows a classification system with all medical devices divided into three classes and each class assigned with different regulatory requirements. The classification system in Thailand, however, is the reverse of international categorization with Class I devices holding the highest risk
- **Product registration of medical devices:** The basic requirements for all cases include the Free Sale Certificate, product catalogues, instructions for use (IFU), and Quality Management Certificate. Additional document requirements that may vary from case to case include clinical data, Certificate of Analysis (COA), batch release, and other product specification
  - **Class I (or licensed devices):** Thai Class I devices require a license for sale in Thailand. Manufacturers must comply with Thai Industrial Standards and in certain cases undergo testing by the Thai FDA. Products in this category include syringes, contact lens, surgical gloves and IVDs
  - **Class II (or notification) devices:** Thai Class II devices need to be registered with the Thai FDA, however, are not required to go through the license process. Manufacturers are only required to submit details on content, production process, and labeling. Thai FDA's Class II includes silicone implants, blood alcohol measuring kits and rehabilitation devices
  - **Class III (or general devices / lowest risk devices):** This category includes products that are not covered by Class I and Class II and are required to only be validated by the Thai FDA. This covers about 90 percent of the medical devices in the country
- **Approval timelines vary for the three classes:**
  - Class I: eight to ten months
  - Class II: six to eight months
  - Class III: two to six days
- **Certification validity also varies for the three classes:**
  - Class I and II medical devices are valid for five years.
  - In case of Class III medical devices, **the validity depends on the validity of the Free Sale Certificate**

112. "Thailand Medical Device Regulation", Regdesk, [Link](#)



## Moderately evolved regulatory systems for medical devices in Thailand

The pre-market approval process devised by the Thai FDA consists of the following systemic series of steps:<sup>113</sup>



113. "Medical devices regulatory services in Thailand", Freyr solutions, [Link](#)

## Medical devices regulatory system at nascent stage in India

### Medical devices regulatory framework in India

The Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare (MoHFW) is the key medical devices regulatory body in India.

Within CDSCO, the Central License Approval Authority (CLAA) is the body responsible for classification of medical devices, enforcing safety standards on devices and conducting post-market surveillance.

Over the past couple of years, Indian medical devices regulatory framework has undergone significant transformation.

#### Regulatory status prior to the release of Medical Device Rules (MDR) in 2017<sup>114</sup>

- Until January 2018, the medical devices sector in India was quite unregulated with only **10 products notified and regulated as medical devices**
- Moreover, if a **foreign medical devices** company wanted to **penetrate into the Indian market**, all it required was an **import license**
- As a result, on identifying that the **existing regulations were insufficient** for India's growing medical devices sector, the MoHFW released the Medical Devices Rules (MDR) in 2017
- The policy **replaced the old list of 20 devices and placed all the medical devices under four classes** with each class holding a different regulatory process

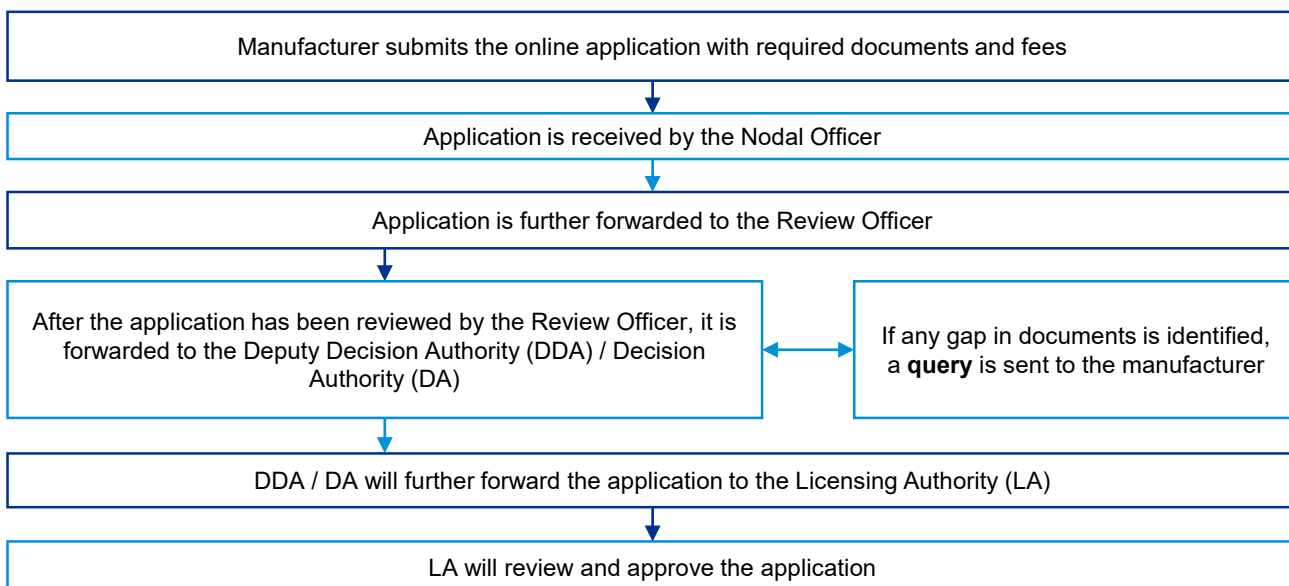
#### Salient features of medical devices regulation (after the MDR came into effect in 2018)

- **Classification of medical devices:** Following the implementation of MDR, all medical devices being sold in India were classified into four categories: Class A, B, C, and D based on the associated risk
- **Class A (low-risk devices):** only require self conformity assessment and registration
- **Class B (low-to-moderate risk devices):** require CLAA to perform an assessment
- **Class C (moderate-to-high risk devices):** require CLAA to perform conformity assessment
- **Class D (devices with a potential risk of illness):** require clinical trials and investigations in addition to CLAA assessment
- **Quality Management System (QMS):**
  - Under the new rules implemented in 2018, a procedure for "third party conformity assessment and certification" through Notified Bodies was introduced
  - The notified body performs QMS assessment at manufacturing facilities for Class A and Class B devices. In addition, the notified bodies can also assist the CDSCO in conducting QMS assessment for Class C and Class D devices' manufacturing sites
  - Further, the CDSCO may also conduct a QMS inspection of the overseas manufacturing site, either through an in-house CDSCO inspector or through a notified body
- **Registration:**
  - The new MDR rules have made it compulsory to procure manufacturing and import licenses for all devices
  - While the manufacturing license for Class A and Class B medical devices is regulated by the State Licensing Authority (SLA), license application for Class C and Class D medical devices is presented to the Central Licensing Authority (CLA)
- **Clinical investigation:** Following the implementation of MDR in 2018, the clinical trial process for a medical device was changed from a four-phase trial to a two-phase trial. The two phases primarily include the pilot clinical investigation (or exploratory study) and a pivotal clinical investigation (or confirmatory study)

114. "Medical Devices Regulatory Priorities in India", Med Device Online, [Link](#)

## Medical devices regulatory system at nascent stage in India

The pre-market approval process devised by the CDSCO consists of the following systemic series of steps:<sup>115,116</sup>



In addition to classification of devices, the government also introduced additional rules in order to make the regulatory framework more comprehensive.<sup>117</sup>



It introduced an online portal called "SUGAM" for license application to manufacture or distribute medical devices in India



It announced the requirement for all medical devices in India to bear unique identification numbers by January 2022



Devices approved in the US, the UK, Australia, Canada, or Japan and complying with CLAA shall not be subject to additional clinical investigation



Manufacturing sites that are not located in India may be subject to inspection by India's CLAA with the applicant subject to an inspection fee of US\$6,000



Registration certificates for medical devices in India are valid for a period of five years and require holders to pay US\$280\* as retention fee

Note: INR1=US\$0.01406, Oanda.com, as on 20 December 2019

115. "Approval process for application received Online Sugam Portal with respect to medical devices", CDSCO, [Link](#)

116. "Application processing by Officials in New Medical Devices", CDSCO, [Link](#)

117. "India's new medical device regulations: 10 things you need to know", MedCity news, [Link](#)

# 6. Conclusion



**The majority of the APAC countries offer positive macroeconomic and demographic conditions for growth in medical devices sector. Some countries stand out more than others.**

Relative comparison of Japan, Australia, China, India, Malaysia, and Thailand on various macroeconomic factors

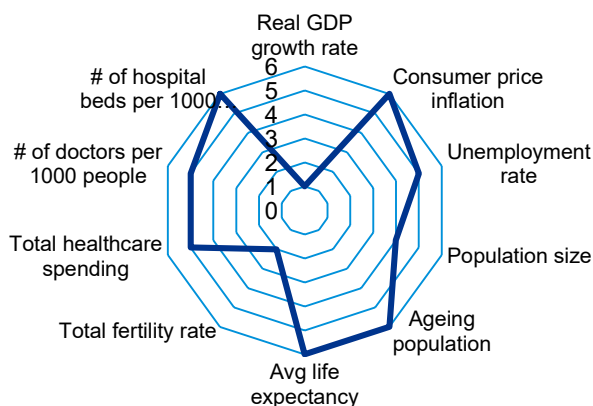
**Scoring scale from 1–6**



Indicates that corresponding macroeconomic factor is **least** favorable for medical devices market in that country

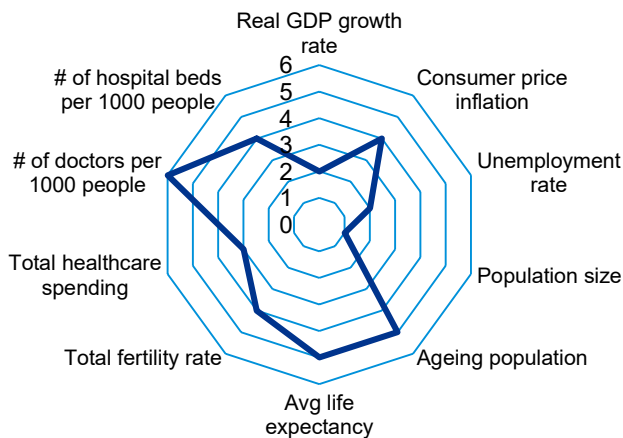
Indicates that corresponding macroeconomic factor is **most** favorable for medical devices market in that country

**Japan**



- Japan's leading position within healthcare indicators such as **average life expectancy, aging population, total healthcare spending** as well as **number of doctors and hospital beds per 1,000 people** offers a background for medical devices development
- On the contrary, **reduced GDP growth rate**, combined with **negative population growth** and **total fertility rate** might hurdle the sector's growth

**Australia**

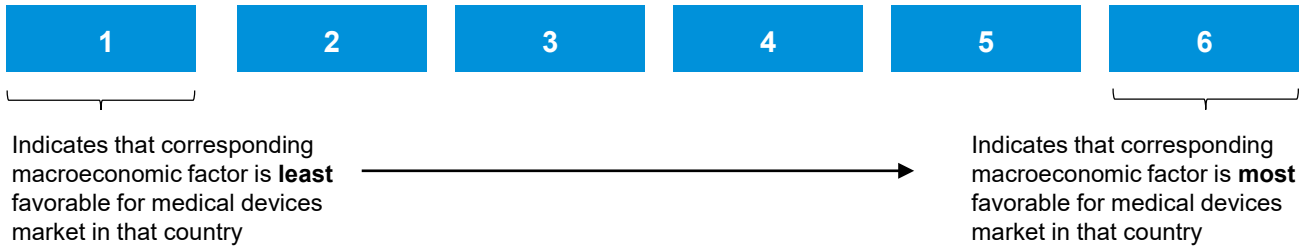


- Australia's **aging population, average life expectancy, and total number of doctors per 1,000 people** have created a lucrative environment for medical devices expansion
- Factors that are likely to hinder the sector's development include **reduced GDP growth rate, limited population increase, as well as relatively low healthcare spending**

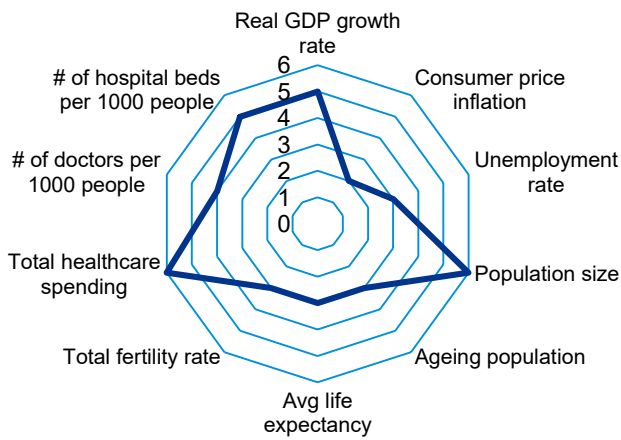
Note: The charts have been created basis information available on secondary sources and subjective judgment of the analyst

Relative comparison of Japan, Australia, China, India, Malaysia, and Thailand on various macroeconomic factors

**Scoring scale from 1–6**



**China**



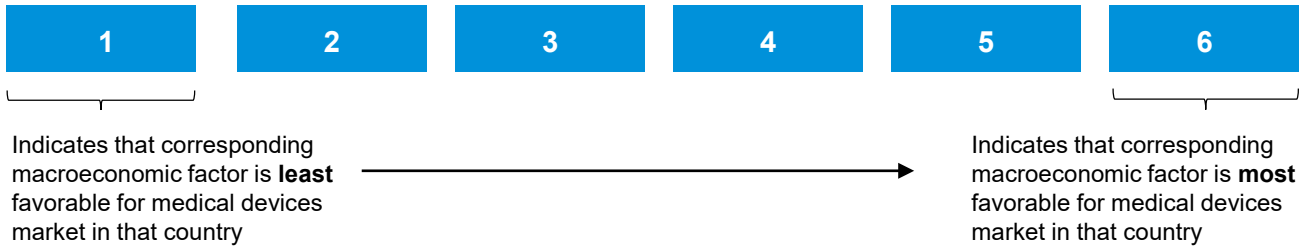
- China's **strong GDP growth rate combined with high population increase and total healthcare spending** has created a positive macroeconomic environment that supports growth of medical devices sector
- In addition, **China's growing aging population** is also likely to contribute to the sector's growth
- Conversely, **high consumer price inflation and unemployment rate** are likely to obstruct its growth



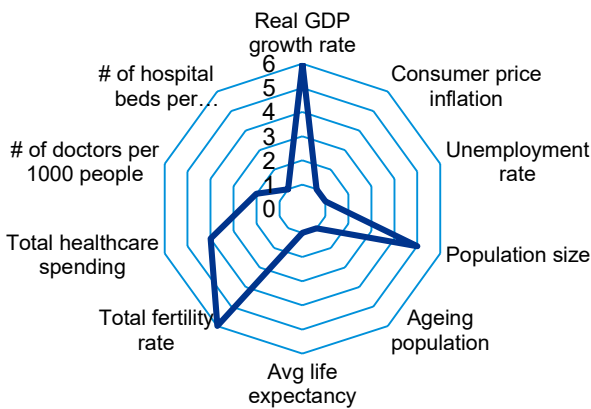
Note: The charts have been created basis information available on secondary sources and subjective judgment of the analyst

Relative comparison of Japan, Australia, China, India, Malaysia, and Thailand on various macroeconomic factors

Scoring scale from 1–6

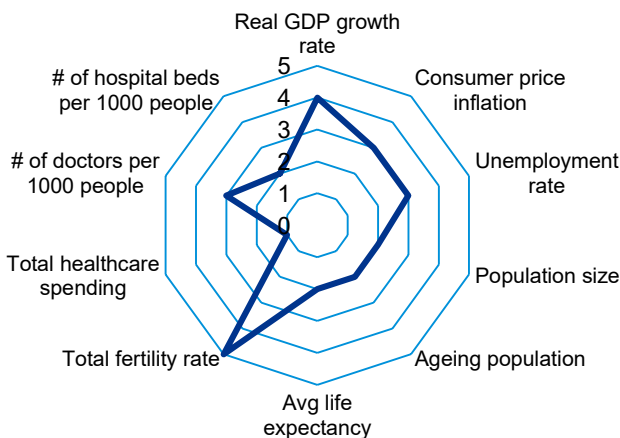


India



- India’s leading position in **GDP growth rate combined with high population increase and rising total fertility rate** have created surroundings that support growth of medical devices market
- In addition, **high infant mortality rate** is also likely to add further impetus to the sector’s growth
- On the contrary, **reduced average life expectancy** as well as **reduced number of doctors and hospital beds per 1,000 people** is expected to hinder growth

Malaysia



- Moderate growth within **GDP combined with high total fertility rate** have created favorable market conditions for development of medical devices in Malaysia
- Conversely, **low healthcare spending combined with reduced population growth and hospital infrastructure** is likely to impede growth of the sector

Note: The charts have been created basis information available on secondary sources and subjective judgment of the analyst

Relative comparison of Japan, Australia, China, India, Malaysia, and Thailand on various macroeconomic factors

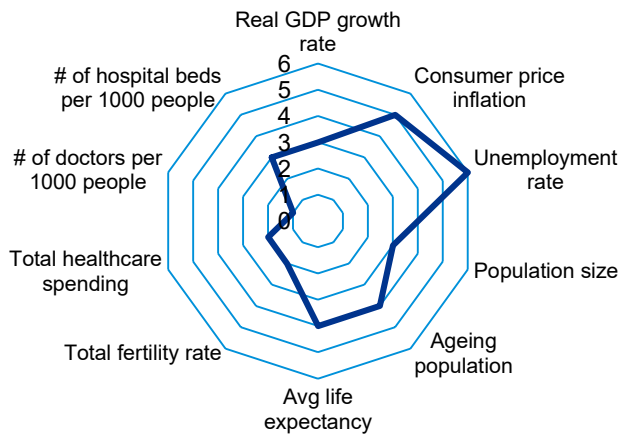
**Scoring scale from 1–6**



Indicates that corresponding macroeconomic factor is **least** favorable for medical devices market in that country

Indicates that corresponding macroeconomic factor is **most** favorable for medical devices market in that country

**Thailand**



- Low unemployment rates and consumer prices inflation combined with moderate growth in aging population are offering a lucrative background for medical devices expansion in Thailand
- Conversely, reduced healthcare spending along with reduced number of doctors per 1,000 people are likely to hamper growth of the sector



Note: The charts have been created basis information available on secondary sources and subjective judgment of the analyst



## Market attractiveness for medical device companies

Global and domestic medical devices companies operating in APAC have been undertaking diverse initiatives in order to incorporate emerging industry trends into their business lifecycles. From establishing MedTech R&D centers to partnering with local distributors, companies are aiming to enhance the quality of care at affordable costs.



		Japan	Australia	China	India	Malaysia	Thailand
Innovation and market trends	Market for medical tourism	Dark Purple	Dark Purple	Dark Blue	Blue	Blue	Dark Purple
	Application of digitalized distribution and route optimization	Dark Blue	Dark Purple	Dark Purple	Blue	Dark Purple	Dark Purple
	Government initiatives/ preferential policies	Dark Purple	Dark Purple	Dark Blue	Dark Purple	Dark Blue	Dark Purple
Distribution network	Presence of open competition for distributors	Dark Purple	Dark Purple	Dark Blue	Dark Purple	Blue	Dark Purple
	Prevalence of third-party players	Dark Purple	Blue	Dark Purple	Dark Purple	Dark Blue	Dark Purple
	Centralization of procurement process	Blue	Dark Purple	Dark Blue	Blue	Dark Purple	Dark Purple
Regulatory landscape	Robustness of regulatory network	Dark Purple	Dark Purple	Dark Purple	Blue	Dark Purple	Dark Purple
	Need for local agent/MAH for foreign manufacturers	Dark Purple	Dark Purple	Dark Purple	Blue	Dark Blue	Dark Purple
	Provision of medical device reimbursement	Dark Purple	Blue	Dark Blue	Blue	Blue	Dark Purple

- For future investment in medical devices, the APAC region presents myriad opportunities. Current forecasts, combining economic, demographic and regulatory factors, suggests that Japan, China and Thailand will see the highest growth rates in the mid-term
- From a distribution perspective, Japan, China and India present lucrative opportunities for distributors and 3PLs that aim to penetrate such markets

*"Thailand's market is very dynamic and that has been beneficial to both our top and bottom line. one area we are looking to develop our presence in Thailand would be in home care. Currently, Thailand's universal healthcare system is very much focused on the care happening inside of the hospital. This is a key opportunity ... If a solution could be found on how to incorporate homecare into universal health coverage this could actually help to reduce overall costs to the system"- Sayan Roy, Managing director, B.Braun Thailand<sup>118</sup>*

*"The launch of Medtronic MedTech Innovation Accelerator in Shanghai will promote closer partnerships between the company and a new generation of MedTech innovators... we are better positioned to upgrade China's MedTech industry, help transform the domestic healthcare system with technology breakthroughs, and drive further toward the realization of the 'Healthy China' vision set out by the central government."- Alex Gu, senior vice president and president of Medtronic Greater China<sup>119</sup>*

Note: The heat map has been created basis information available on secondary sources and subjective judgment of the analyst

118. "Sayan Roy – Managing Director, B. Braun Thailand", Pharma Board Room, [Link](#)  
 119. "Medtronic Launches Medtech Innovation Accelerator in Shanghai", Medtronic, [Link](#)

# 6. Way forward



As governments across APAC countries are working towards controlling overall healthcare costs, medical devices companies are expected to continue to innovate products that are high in quality as well as competitively priced.

The medical device industry in APAC region needs to adopt a three-pronged approach towards providing this value-based care. This includes **access, collaboration and innovation**.<sup>120,121</sup>



### Access

The government need to strive to ensure **access to medical diagnostic and treatment devices for patients**, by working in tandem with **regulators, manufacturers, healthcare providers and payers**

1



### Collaboration

Companies need to create a **platform for knowledge exchange and engagement** with stakeholders to develop solutions that meet growing healthcare demands in APAC

2



### Innovation

Promote a **cost-effective, value-based approach** to healthcare in APAC by developing innovative medical technologies for advanced healthcare outcomes

3



120. "Innovation and better availability of medical devices can help India stay on top of its health", Your Story, [Link](#)  
121. "Improving access to high quality healthcare across Asia Pacific", ApacMed, [Link](#)



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