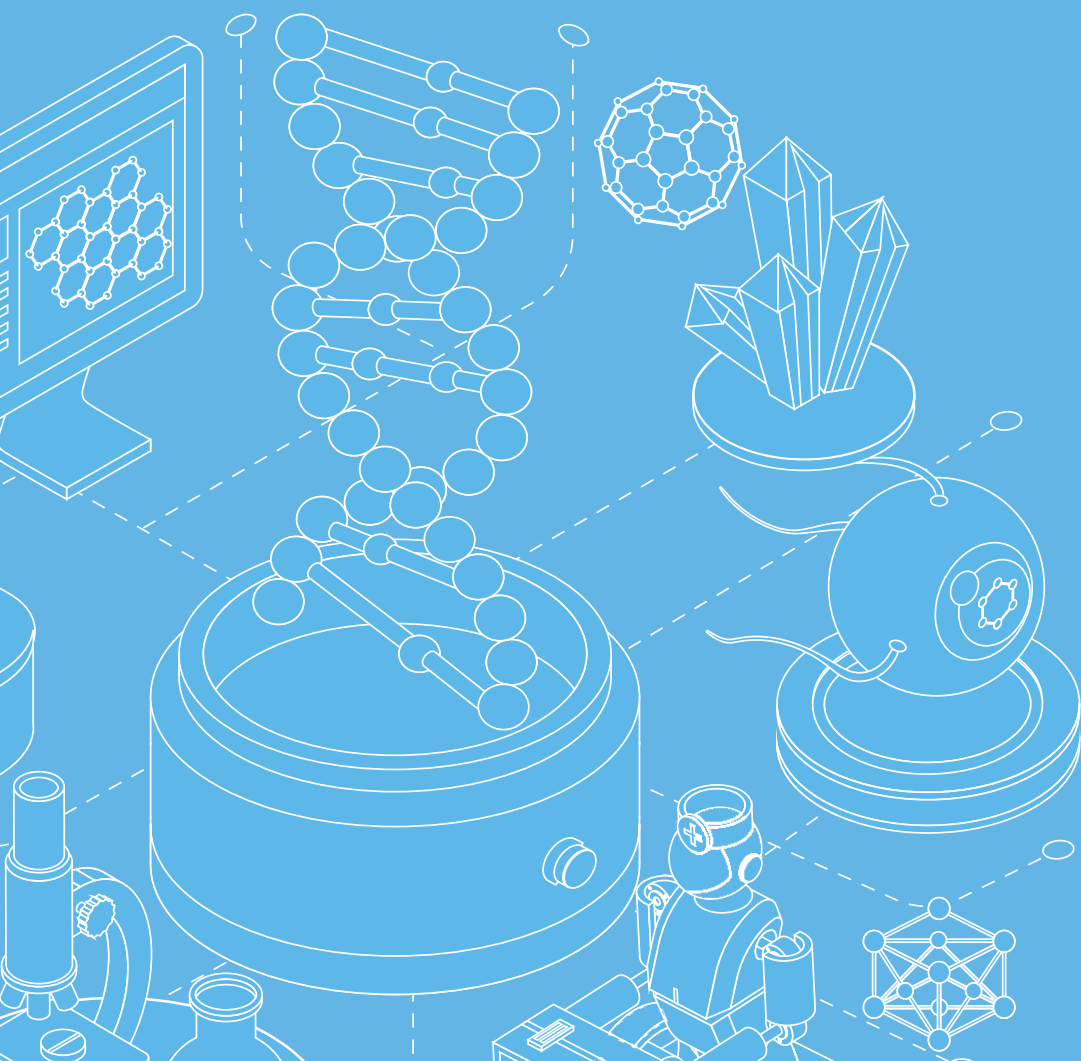




Chinese Medical Device Industry

How to thrive in an increasingly competitive market?



Medical device market in China

The Chinese medical device industry is a large and growing market. In 2019 it reported revenues of RMB 629 billion, up from RMB 308 billion in 2015 – over doubling in size. In 2020, due to COVID-19, there was a rapid surge in demand for a range of medical devices, such as medical masks, nucleic acid test kits and ECMO machines. As a result, it was estimated that industry revenue jumped to over RMB 800 billion in 2020¹. With an annual growth rate of around 20% since 2015, the industry has consistently outpaced GDP growth in recent years.

China now boasts over 26,000 medical device manufacturers, indicating a proliferation of many small manufacturers². As of 2019, medical equipment made up nearly 57% of the market, followed by high end consumables (20%), then low-value consumables (12%) and in vitro diagnostics devices (IVDs) (11%).

Figure 1: Market size of medical devices in China, 2019 (RMB billions)



Source: E-share: Blue book of medical device industry in China, EIU; Deloitte research, analysis & interview

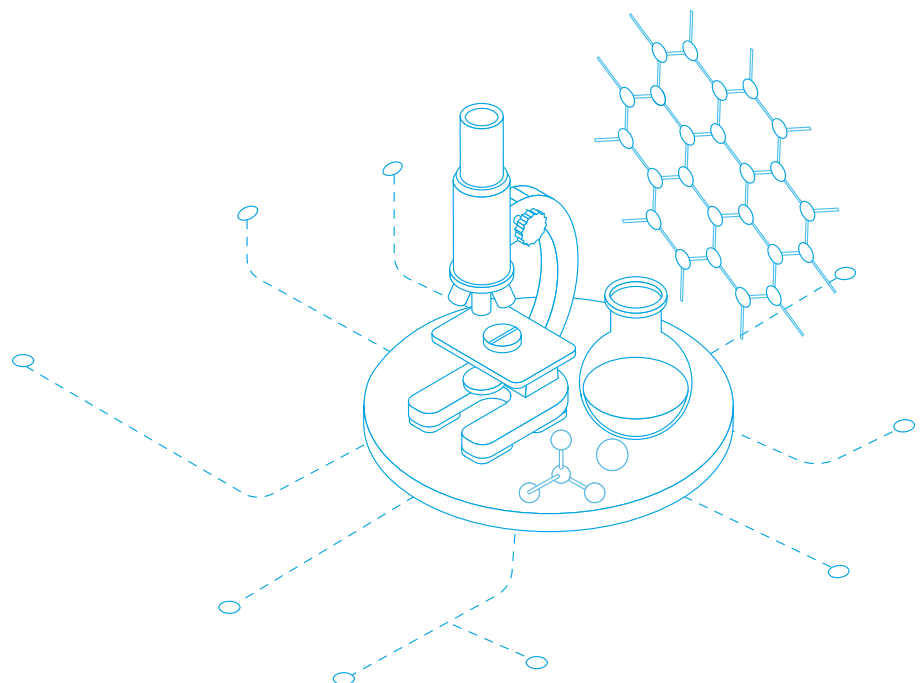
The domestic industry is concentrated in four key regions: the Bohai Rim (centred around Beijing), Yangtze River Delta (including Shanghai), Pearl River Delta and Central China (including Wuhan, Chengdu and Chongqing). Local governments often support the development of medical device industrial zones with preferential policies for setting up within the zone, such as rent reductions, settlement bonuses or product registration bonuses. The largest of such industrial parks (in terms of number of enterprises) is China Medical City in Jiangsu province, with over 110 medical device manufacturers.

China now accounts for around 20% of the global medical device market. It

is a growing market and is expected to continue this upwards trajectory into the future, driven by a number of key drivers:

1. an aging population resulting in an increasing prevalence of chronic diseases,
2. income growth leading to more healthcare spending per capita,
3. the proliferation of more healthcare clinics and hospitals, and
4. policies resulting in low premiums on drugs (meaning that industry players are seeking alternative revenue sources).

As the Chinese economy further grows, healthcare users' focus will increasingly move from treatment towards prevention.



Who are the players?

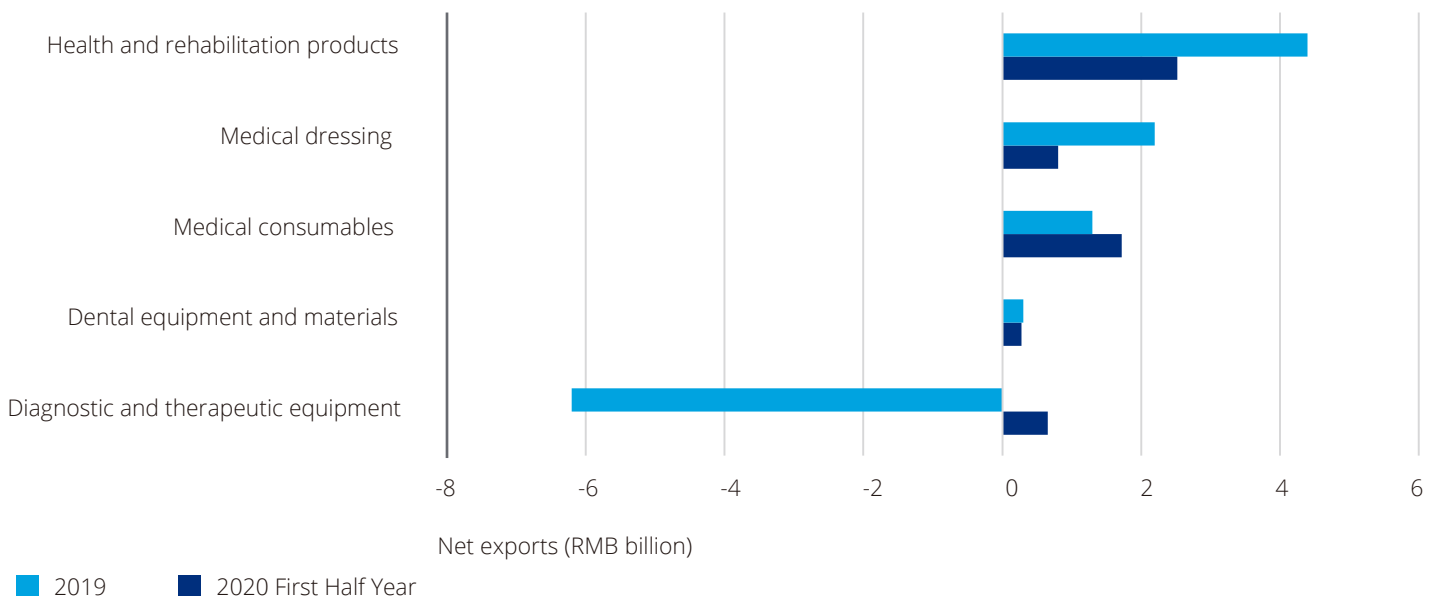
The majority of domestic manufacturers are small- to medium-sized business with capacity centred around lower-value added devices, such as low-value consumables. These small domestic firms dominate the mid- to low-end market. In contrast, the industry is still highly dependent on imports for high-end devices. A handful of foreign brands dominate the high value medical device market. However, the market share of domestic brands in the high value segment has increased over the past 10 years from around 20% to around 30%.

China is also becoming an increasingly important player in the global medical device market. From 2015 to 2019, Chinese foreign trade in medical devices grew at nearly 10% per year (outpacing worldwide growth), making the country an increasingly larger proportion of the international medical device trade market. In 2019, China's medical device exports and imports reached USD 29 billion and USD 27 billion, respectively. Disposable consumables, medical dressing and low-end medical equipment together made up the majority of exports, while around 70% of imports were

diagnostic and therapeutic equipment (mostly high-end devices).

2020 was a disruptive year for the industry, due to COVID-19. However, China saw an overall rise in exports in the first half of 2020, growing 22% compared to the previous year's first half. Perhaps unsurprisingly, the strongest area of export growth was medical consumables (such as masks), with 43% growth. At the same time, imports fell by 18%, decreasing in all categories except medical dressing³. This meant that, in contrast to previous periods, China experienced net exports for all categories.

Figure 2: Net exports (exports - imports) of medical devices by product category (RMB billion)



Source: Customs import and export database; Deloitte research and analysis

Note: 2020 First Half Year covers a shorter time frame than full year 2019, so the magnitude of the results are generally smaller. This period covers the height of COVID-19's disruption in China, so it does not necessarily reflect long-term trends in imports and exports.

China is thus increasingly becoming a market foreign firms cannot afford to ignore. However, like all nations, it has its own distinctive regulatory and competitive environment. Device makers need to consider how best to position themselves in the market.

Regulatory policies are changing and impacting foreign brands

Medical equipment in China is ranked into three classes according to risk: Class I (least risky), Class II or Class III (most risky). Production requires a production license and product registration, while operation requires an operation qualification. In recent years, foreign manufacturers have been subject to increasingly stricter supervision. In 2018 the State Council explicitly called for more overseas inspections of medical devices⁴. Consequently, in 2019 there was a dramatic increase in the number of inspections by the National Medical Products Administration (NMPA). This trend will likely continue into the future (excluding interruptions caused by COVID-19). Some provinces, however, are piloting programmes that facilitate expedited registration and approval for innovative products with urgent needs.

In practice, policies tend to favour domestic-based manufacturing in a number of ways. China's "Made in China 2025" has targeted that 50% of mid-to-high-end medical devices will be Chinese-made by 2020, with this goal raising to 70% in 2025 and 95% in 2030⁵. Domestically manufactured products face lower registration fees

and can receive a variety of support in terms of product research, market entry approval and downstream procurement⁶.

Manufacturers have noted that local and national governments have pressured hospital to purchase locally-made goods. State insurance funds may refuse to reimburse certain foreign devices, for instance⁷. Six provinces have published a "permitted imported medical equipment catalogue". Unless there are no medically or technologically comparable domestic devices, the catalogues recommend that only listed products should be imported. While hospitals are not strictly prohibited from importing products not on the catalogue, they are advised to give careful consideration before doing so.

However, full localisation of the medical device market is not practical, especially since imports play an important role in disseminating new innovations and technology in the industry. Market opportunities, therefore, still exist for foreign firms.

How to enter the Chinese market

If a manufacturer has decided to enter the Chinese market, they must then decide how to enter the market. There are broadly three ways to enter the market:

1. rely purely on importing,
2. directly invest in setting up a local operation, or
3. partner with an OEM.

Figure 3 below sets out the drivers for each choice.

Figure 3: Decision drivers on entering the Chinese medical device market



Source: Deloitte research, analysis & interviews

Importing allows for faster market entry (which is important if the market will soon be saturated) and requires relatively lower capital investment. Imports also help protect against the risk of IP theft. However, it is harder to manage brand image without a local foothold and Chinese hospitals may face relatively higher regulatory barrier to purchasing imports⁸. Imports are most suitable for smaller scale companies, with lower brand awareness, who lack the funding and management capacity to operate a Chinese representative office.

Companies with prominent product offerings in high growth segments may instead choose to set up a local operation. This requires more capital investment and takes longer to enter the market, but in the long run manufacturers can lower production costs and develop localised after-service capabilities. Foreign companies can set up a local entity via a joint venture, M&A or greenfield investment⁹. Chinese cross-border M&A and JV medical device deals have

outpaced other areas of healthcare in recent years, with local firms looking to leverage the foreign players' comparative advantages in high-end technology¹⁰.

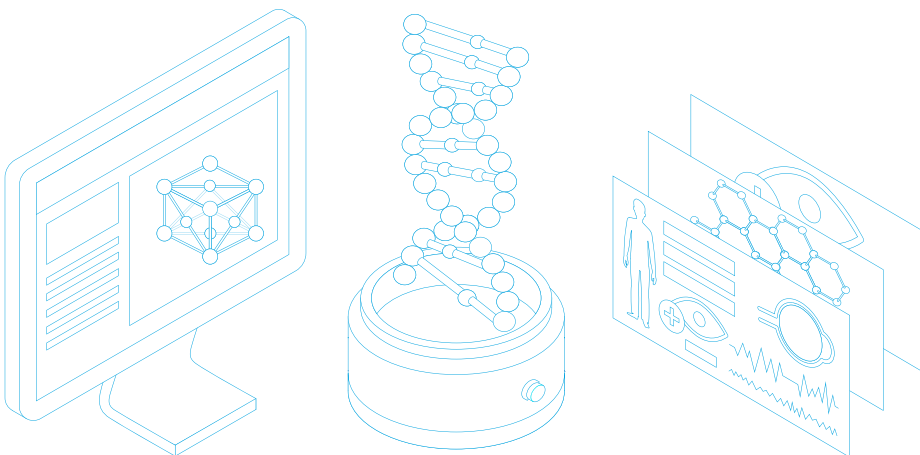
Alternatively, companies can consider partnering with a local OEM. By using a local OEM partner, the company can meet local production mandates, thereby reducing regulatory barriers to market entry. Compared to direct investments, it also requires less capital and facilitates quicker market entry. However, there is a greater risk of IP/technology leakage. Foreign companies need to work hard to find a qualified local OEM partner that they can trust and then continuously monitor product quality. This approach is thus more applicable for more generic products or products whose IP can be confidently safeguarded during the manufacturing process.

Regardless of the market entry model, foreign firms will likely rely on a distributor to facilitate sales to hospitals and clinics.

Choosing the right distributor for new entrants

Choosing the right distributor cannot be understated when it comes to thriving in the Chinese market. A good distributor promotes the manufacturer's products, influences key opinion leaders (KOLs), including local government, and can help identify important accounts and markets. They can take advantage of their broad network of hospitals and clinics to enable a wide spread of customers, and can help ease cash flow pressure for manufacturers as the hospitals themselves often have long payment cycles (over a year). The right distributor will have technically competent sales staff who can provide key support services such as tutorials, use guidance, troubleshooting and complaint mitigation.

However, the very top, established distributors may not necessarily be the best choice for new entrants. Such distributors will have high standards when it comes to choosing to represent a foreign device manufacturer. Since they already have an established set of products, they may be unwilling to take on new products that compete with their current selections. Additionally, their terms may require yielding a higher proportion of profits compared to smaller distributors.



In the past, the traditional distribution model in China could involve multiple middlemen between the manufacturer and hospital. Manufacturers would contract with a large distributor, who would then subcontract with smaller distributors who would individually engage with each hospital.

This system resulted in multiple rounds of mark ups, and encouraged hospital procurement decisions based around securing commissions or kickbacks¹¹. In an effort to control costs in the supply chain, the Chinese government has introduced a "two invoice" system that only allows one distributor: one invoice between the hospital and the distributor and one invoice between the distributor and the local manufacturer¹².

This system first emerged in the pharmaceutical industry, which has acted as a harbinger of later reforms for the medical device industry. Already, the pharmaceutical industry has witnessed further movements towards a one invoice system, effectively removing all middlemen, suggesting the possible future for the medical device industry.

What's the best way to distribute in China?

When entering the market, foreign players have a number of possible distribution models to choose from:



1. Rely solely in-house marketing and sales

This model is favoured by large global MNCs, since they have the capacity and economies of scale to develop large, sophisticated in-house market and sales teams.



2. Rely on in-house marketing capability but use distributors for sales

This approach is favoured by large scale MNCs with a significant proportion of sales in China; it allows such firms to maintain their brand images and influence over key areas.



3. Directly market to key hospitals in tier-1&2 cities, while relying on distributors' marketing capabilities in tier-3&4 cities

This model is common among foreign firms that have been in China for a number of years.



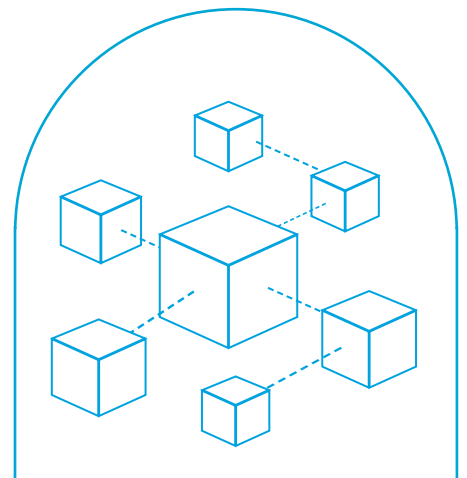
4. Rely on in-house capability for sales and distributors' capability for marketing

This model is more common among the pharmaceutical sector where government is pushing for a "one-invoice" system (i.e. sales cannot go via a middleman).



5. Rely entirely on distributors for both marketing and sales

This model is most commonly adopted by new entrants to China, since it is relatively simple and such companies are unfamiliar with the local market.



Key considerations in relation to incorporation a business in China are shifting from the traditional labour costs and infrastructure towards tax incentives, local financial subsidies and industry compliance support from local governments.

Feeling the price pressure

As noted earlier, there has been a rapid growth in new manufacturers, putting competitive pressure on foreign brands. This trend is only set to continue: "to cope with the raging COVID-19 epidemic in the first months of the year, Chinese authorities [have] accelerated the approval of medical devices, according to the National Medical Products Administration"¹³.

Government reforms to reduce healthcare costs have made hospitals increasingly price sensitive. In 2012 Sanming city, Fujian province, began a comprehensive reform of their hospital system to reduce costs¹⁴. Reforms included a crackdown on hospital mark-ups, staff wage changes to reduce incentives for commissions, centralised procurement and greater use of generic drugs. The reforms successfully reduced hospital costs in the city, and the central government has, therefore, announced a national rollout of similar reforms using Sanming as the model, including annual price adjustment assessments¹⁵.

In May 2019 the eighth meeting of the Central Committee for Deepening Overall Reform was held.

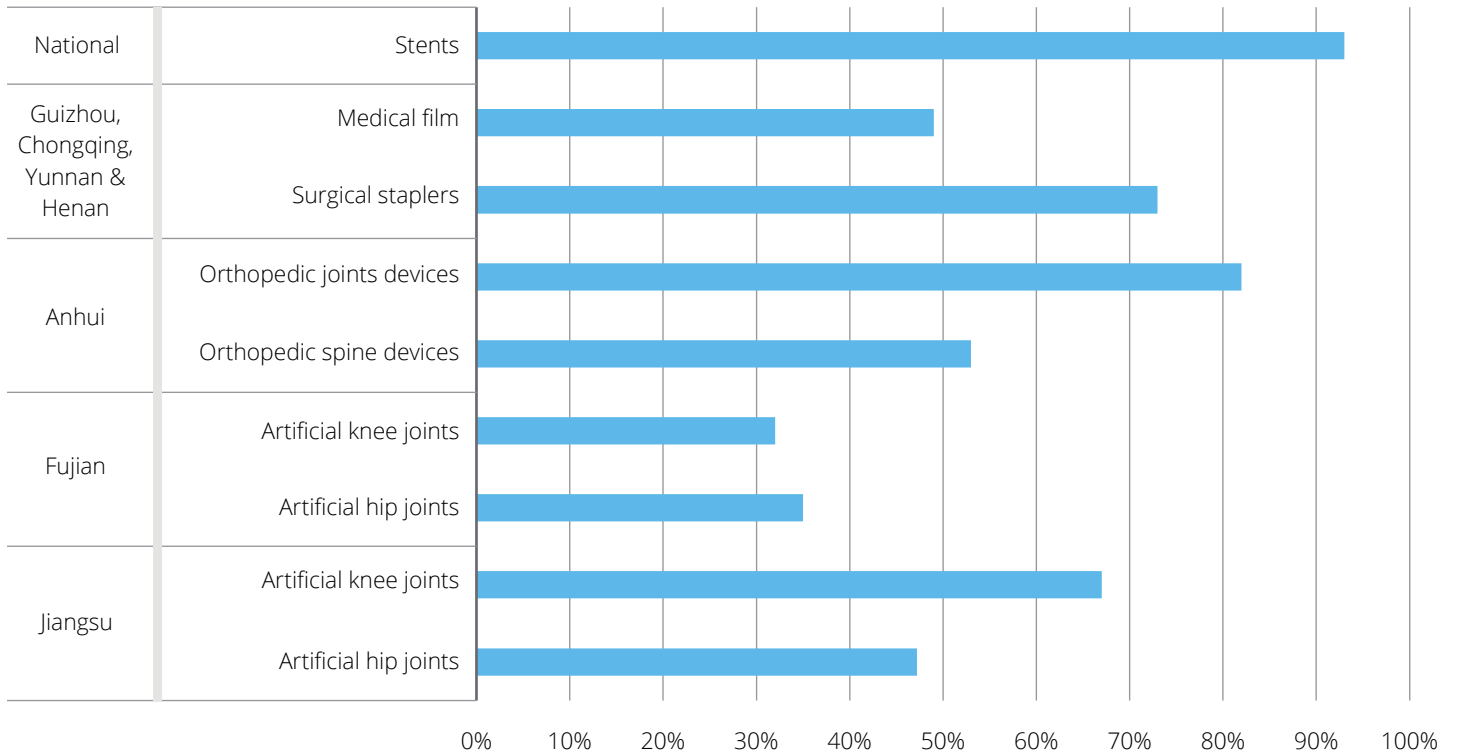
The committee approved its "Reform Plan for Governance of High-Value Medical Consumables". As part of this plan, the Government was tasked with looking into centralised volume-based procurement (VBP) of high-value medical consumables¹⁶.

The Chinese government has thus begun to use centralised VBP to target price falls in specific devices. In 2020 China introduced a bidding system for the centralised procurement of heart stents, purchasing enough stents to meet over 70% of estimated hospital demand. Eight companies (six domestic and two foreign) had winning bids. This system has led to dramatic reductions in the price of stents, with the Chinese government reporting average price reductions of over 90% compared to the previous year¹⁷.

Following this first round, the government has indicated that it is collecting data from each province to prepare for its next round of procurements, which will involve artificial hip joints, artificial knee joint, automated external defibrillators, occluders, orthopedic materials and surgical staplers¹⁸.

With the encouragement of the national government, local governments have pivoted towards centralized VBP. For example, across the country, 26 provinces have centralised procurement of intraocular lenses¹⁹. In December 2020, Jiangsu province completed its fourth round of procurement. This round for medical film and surgical staplers, following ones targeting stents, artificial hip joints and knee joints. The province reported price falls from 50% to 96% across the various categories of goods. Likewise, the four provinces of Guizhou, Chongqing, Yunnan and Henan have announced an alliance for the procurement of a variety of medical devices, including hernia mesh, staplers and medical film, reporting average price falls over 60%. Hubei Province has also carried out similar reforms with similar reductions in prices²⁰.

Figure 4: Average price reduction of selected items from government VBP rounds



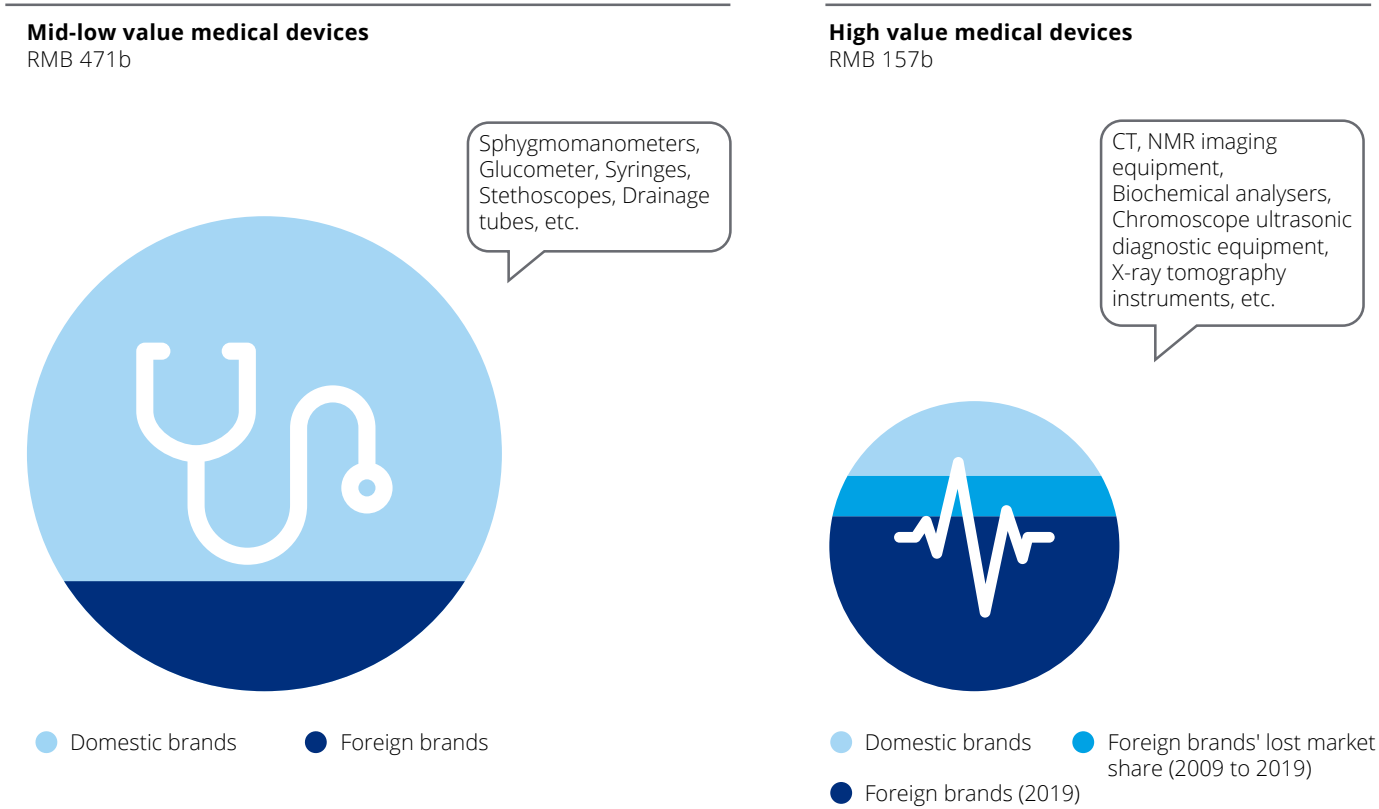
Source: Deloitte research, Saibailan (2020)

Under pressure to reduce their costs, hospitals have pivoted towards local manufacturers who are generally more cost-competitive. As a result, local firms are gaining market share, especially in the Imaging and IVDs sub-sectors²¹. Four of the biggest ten IVDs companies in China now are local firms²².

For a long time, foreign brands have dominated the high-value medical device market, where price sensitivity is lower. However, as noted earlier, their market share has fallen in the past 10 years from around 80% to 70%. This trend is only expected to continue into the future. Nevertheless, even if

their market share falls relative to local firms, foreign firms can still expect to enjoy revenue growth in the future due to the overall growth of the industry. If they can position themselves in the market correctly, foreign firms have a healthy outlook in China.

Figure 5: Market size and competitive landscape for foreign firms



Note: The shaded area represents approximate market share; the size of the circles themselves reflects the relative market size differences

Source: Qianzhan industry research institute; Deloitte research, analysis & interviews

How to thrive in a price competitive market?

While such reforms have helped hospitals keep a cap on costs, they have put pressure on medical device manufacturers' margins. So how can device suppliers thrive in such a market?

One method is to target volume rather than product margins. The size of the Chinese market means that the overall level of profit that can be made in the market can still be substantial even if the margin on each individual product is small. Boston Scientific, for example, won the right to supply two types of stent products in the recent round of centralised procurement, securing for itself a large source of revenue compared to supplying an individual hospital or clinic²³. This revenue, however, was secured at a cost of lower individual unit pricing.

This volume-over-margins model requires large economies of scale to be viable, however. Markets which move towards large-scale centralised procurement are, therefore, over time likely to see increasing concentration and commoditisation.

Most medical device manufacturers, however, would like to avoid seeing their products become mere commodities and their margins squeezed. If a supplier is able to

establish a high-value, technical niche they cannot be so easily undercut by local suppliers. Such products are also less likely to become the targets of centralised procurement schemes. Device manufacturers are also increasingly considering how services can be added to the products, since a products+services model is harder to commodify. China does not have the capacity to develop or manufacture all its medical device needs and there is still a substantial market for high-end foreign brands.

Embracing the Internet of Medical Things is also an opportunity to add value while avoiding a squeeze on margins. The Internet of Medical Things (IoMT) comes from the intersection of data and smart medical devices. It is "a connected infrastructure of medical devices, software applications and health systems and services"²⁴. The IoMT is transforming medical device manufacturers' role in the global healthcare system. If IoMT device makers can demonstrate to hospitals and patients the value and benefits of connected medical devices, there is capacity for rapid value-added growth in the industry²⁵. However, in China, when it comes to collecting or accessing the broad data necessary to maximise the value of IoMT, multinationals are at

a distinct disadvantage compared to local technology firms. Foreign manufacturers may need to consider partnership with a domestic firm if they want to compete in this area.

Multinational medical device companies need to revisit their existing China business model and supply chain arrangement to mitigate the current short term price and cost pressure to capture future market growth in China. When it comes to business model optimisation, careful tax assessment and planning should be taken into consideration. Manufacturers should make full use of local industry preferential policies and build up a tax-optimized worldwide trade and supply chain model. In particular, changes in the market need to be factored into when considering transfer pricing policies and prices on imported materials and supplies. For instance, if a medical device company takes on more responsibility in China, its Chinese-based profits will likely increase. Additionally, if they engage in a high volume-low margin strategy, their import prices may need to decrease, affecting both transfer prices and customs values. The combined impact of these changes on tax are often overlooked, yet material.

China for China strategy

Getting local in operation

With rising geopolitical tensions between China and the West, many foreign firms in China are pivoting towards an "In China, For China" strategy. This is to say, investing in production in China for the purpose of selling to local markets, rather than exporting. This strategy reflects the increasing size and importance of the Chinese market. By moving production closer to its end market, manufacturers with domestic set ups can respond to customer demand more rapidly, and often more cheaply²⁶.

Localising the supply chain in China does not just mean replicating the foreign supply chain, but cheaper. Manufacturers should consider it an opportunity to invest in innovation for the Chinese market. The Chinese government has since mid-2000s encouraged greater innovation, such as tax policies favourable to investment in R&D. This has seen China's economy moving from one dominated by imitation towards one where there is the infrastructure and resources to reward innovation by firms²⁷. To this end, the economy has developed a surrounding ecosystem that facilitates innovation.

For instance, the nation is taking a leading role in the development and

deployment of 5G technology. China will account for nearly 80% of global subscriptions by the end of 2020. Over 10% of mobile subscriptions in the country now use 5G²⁸. The technology has an important role to play in the medical device sector, particularly in the aforementioned IoMT, smart hospitals and the development of wireless body area sensor networks. If such networks can be developed, they will spur improvements in disease deduction, monitoring and post-surgery feedback²⁹. During the height of the COVID-19 pandemic, 5G facilitated remote diagnosis in Wuhan³⁰. The country has already become the third largest global market for smart healthcare after USA and Japan³¹.

One should also not overlook the financial incentives available via localisation, such as lower company income tax rates of 15% and reduced or eliminated VAT. These and other financial incentives are key financial factors in optimising device makers' business models and will be affected by their chosen strategy.

So how can foreign device makers get more local? Joint ventures (JVs) are a common form of investment for foreign device makers entering the Chinese market. By partnering with

a local company, foreign investing companies are able to take advantage of their partner's local know-how, which can be particularly important in heavily regulated industries such as healthcare. The right partner helps connect foreign device makers to their local eco-system of suppliers, customers and government relationships, thereby helping the firm dive deeper into the Chinese market.

JVs also act as a relatively simple way to indirectly take advantage of China's capital markets, since, under a JV, a proportion of the capital costs will be met by the local partner.

On the other side of the coin, many local device makers are looking to partner with foreign manufacturers to shorten their time to market for new products. As Chinese companies grow in sophistication, they also increasingly view such Sino-foreign partnerships as a means to expand their presence in overseas markets.

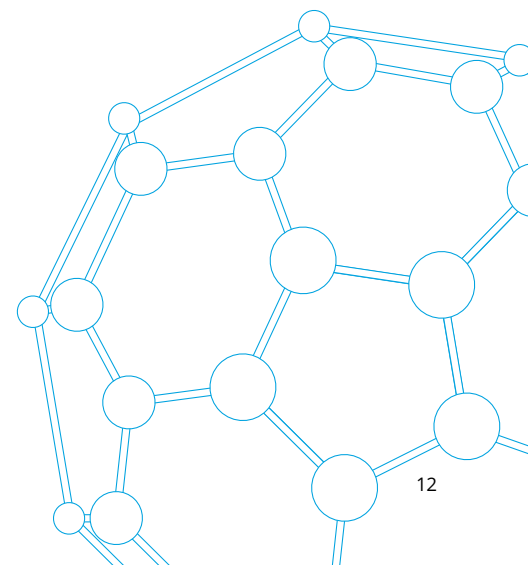
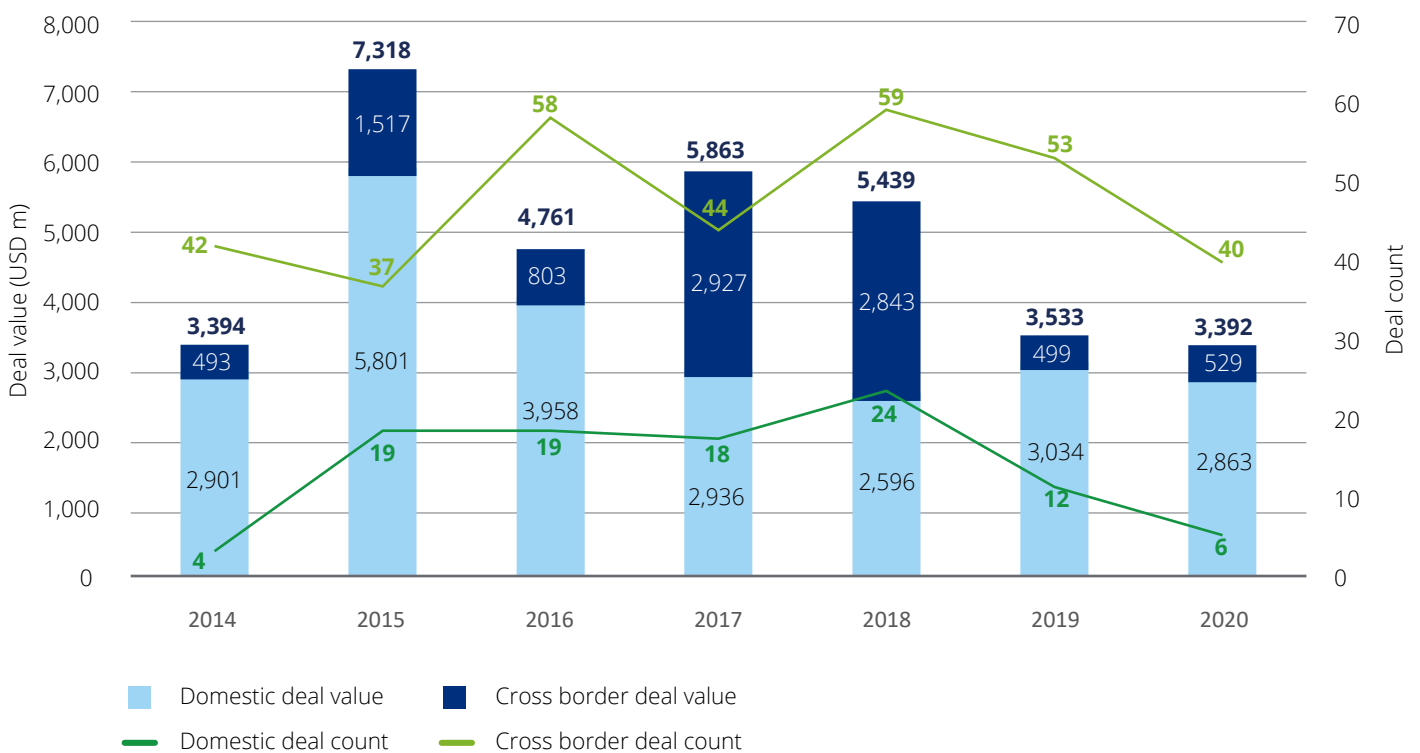


Figure 6 below shows the trend in domestic and cross-border medical device M&A deals in China (including JVs). As can be seen, cross-border deals are relatively more volatile in terms of deal size, since the former category is more likely to include mega-deals. Due to the heavy reliance on imports for high-end devices, domestic firms are looking towards such deals for access to new

technology or products. Despite the tough global economic conditions, medical device M&A activity remained relatively steady in 2020, reflecting the importance of the industry during COVID-19, though the number of cross-border deals fell. One of the largest deals of the year was for Dirui Industrial, a Chinese-based manufacture specialising in disease-testing devices, including for COVID-19.

Figure 6: Domestic and cross-border medical device M&A deals in China



Source: Deloitte 2020 China life sciences and health care M&A trends, Mergermarket

The Chinese market, like all markets, is unique. Going local means accepting that the Chinese division needs some degree of autonomy. A common factor in success stories for foreign businesses in China is empowering the local entity to make meaningful decisions that reflect the local

circumstances. Rather than treating the Chinese division's management as merely a figurehead for headquarters, firms that have thrived in China treat China as stand-alone market, and form their strategies in light of this. This, however, is not to be confused with lax or poor governance and oversight.

Getting local in capital markets

Device development is relatively capital intensive, with long R&D cycles. As a result, access to capital is an important consideration for manufacturers. Chinese capital markets are large but uneven, with some company types benefiting from years of easy access to capital, helped by government policies.

An overview of China's capital markets

China's capital market has traditionally been relatively biased towards debt, with large national banks favouring loans to state-owned enterprises (SOEs). This bias is likely because SOEs are viewed to be implicitly backed by the government³³. In the past, this led to a growth in shadow banking, wherein SOEs would then pass on the loans to other companies. However, authorities have clamped down on such practices in recent years³⁴. As Chinese banks develop more sophisticated risk management strategies, banks are increasingly more willing to lend directly to small and medium-size enterprises themselves.

Chinese bond market is large, but dominated by interbank lending. The exchange-traded proportion of the market, which is regulated by the China Securities Regulatory Commission, is relatively small. Defaults in the market have risen steadily since 2014³⁵. The Chinese government has shown an increasing willingness to let state-linked firms default which has put pressure on the working assumption that SOEs are implicitly backed.

The two largest mainland stock exchanges in China are the Shanghai Stock Exchange (SSE) and the Shenzhen Stock Exchange (SZSE). SOEs make up a significantly proportion of China's stock markets.

There are relatively low levels of institutional investment and trading, and high levels of retail trading³⁶. Foreign ownership levels are low, reflecting years of restricted access; however, the government has recently increased ease of access to Chinese stock markets for foreign financial firms. Despite the size of the stock market, equity is a relatively low proportion of capital raised in China³⁷. Overall, Chinese firms are more likely than international counterparts to raise capital via debt.

How can a foreign device maker access this capital market? Foreign firms may be eligible for assistance by locating domestically. JVs are a common way for foreign companies to access the wider Chinese capital markets via the investments of the local partner. Indeed, in our experience access to capital is a core driver for foreign firms looking into JV in China³⁸.

Seize your opportunity

The medical device Chinese market is one of opportunities. It is both large and growing. But device makers must think carefully about how they wish to position themselves in the market. Do you have the capacity to play the volume game? Or should you focus on how you can develop higher value added products that are not susceptible to commoditisation? With the right strategy, the Chinese medical device market provides significant opportunities.

Firms should look to how they can secure support from the government when entering the market. Industries that align with the nation's strategic goals are more likely to be able to secure help from the Chinese government. Local Chinese governments often compete against each other and may be willing to offer assistance for setting up within their desired medical device industrial zones, such as settlement bonuses or favourable loans.

With an aging population that will require more long-term medical care, rising income growth and the proliferation of healthcare clinics and hospitals, China is set to be an increasingly important player in the global medical device market. Manufacturers should consider how they can capture a stake in this growth.

Local market innovation continues to speed up. Thus, to stay ahead and to differentiate themselves, manufacturers need to offer the latest technology and product solutions to the Chinese market. Large global multinationals will need to review their governance and operating models, managing their business close to the market, to stay agile and facilitate fast decision-making with "Chinese characteristics".

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⁹For a more comprehensive look into both the advantages and potential pitfalls of establishing a joint venture in China (compared to other investment methods), see our report "Sino-Foreign Joint Ventures after COVID-19: what to expect?" available here: <https://www2.deloitte.com/cn/en/pages/finance/articles/sino-foreign-joint-ventures-after-covid-19-report.html>

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