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GOING LOCAL: STRATEGIC CONSIDERATIONS FOR MEDTECH MANUFACTURERS IN CHINA

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A rise in regulatory policies in China favoring domestic products puts a premium on companies achieving some level of localization in the country. Establishing a China-based manufacturing footprint is crucial to this end, but the exact definition of "local" is evolving. Context and considerations from Grace Wang and Helen Chen at L.E.K. Consulting.

A regulatory trend toward localization along with a multiyear drive to supercharge domestic innovation and favor domestically manufactured products, including in the medtech space, is complicating the operating environment in China for foreign multinationals.

The Chinese market is an important target for medtech companies, particularly as inflation and recent cost pressures in the US have restrained growth. Medical devices account for less than 8% of overall healthcare spending in the US, so companies need to be cost efficient and sustain growth via other markets.

China is already the second largest medtech market in the world and its population includes the largest patient pools globally for many diseases. Experts expect growth of China's medtech market to continue to outpace the global market. Yet, many companies are not prepared to navigate the regulatory changes and subsequent requirements there, including the growing necessity in China to establish oneself or one's products as "local."

The Backdrop

Since May 2020, China has encouraged "internal circulation" as the key driver of economic growth. Internal circulation refers to the idea that the economy should be driven by domestic supply and domestic consumption. The government has advanced the concept using a range of carrot and stick policies at the national level that encourage onshore manufacturing and favor local products.

The focus of this effort to bring more manufacturing onshore is shifting toward medical devices. This will have significant impacts on multinational companies (MNCs) in medtech, which will need to adapt to ensure they maintain solid footing in the market.

Regulators in mainland China have adopted multiple policies that need to be taken into consideration by MNC medtech manufacturers when planning for future operations.

A recent case in point is *Order 551: Guidance of Government Procurement of Imported Products* launched by the Ministry of Finance and Ministry of Industry and Information Technology in May 2021. Known as the Buy China policy, Order 551 provides guidance on the procurement budget for 315 local products, including 178 medical items. The policy creates market access barriers for foreign MNCs that have a leading position in many subsegments of China's medtech market.

L.E.K. Consulting's survey of hospitals in China found that 60% had either already implemented Order 551 or planned to do so in the next six months. Only 18% said they were not likely to implement the order and 8% had never heard of it. More significantly, six months after Order 551 was issued, the number of hospitals restricting the use of imported medtech products where possible jumped 10-fold. (*see Figure 1*).

At the provincial level, a number of local authorities have required an import product evaluation, under which hospitals need to provide evidence to justify why they purchase imported medical equipment.

At a broader level, the policies supporting and favoring domestic products have been trending in a similar direction for several years.

A *Made in China 2025* policy was first launched in 2015 to increase the proportion of domestically made, mid- to high-end devices used in county-level hospitals to half by 2020 and to 70% by 2025, and to increase the share of domestic core medical device components to 80% by 2025. The policy is supported by the expedited registration of domestic devices and "buy local" procurement.

National guiding development plans, such as the 13th Five Year Plan (2016-2020) and the 14th Five Year Plan (2021-2025), further support the localization push. The more sector-specific *Medical Equipment Development Plan* of the 14th Five Year Plan, launched in December 2021, emphasizes innovation, standardization, collaboration, and talent recruitment to help leading domestic companies grow at 15%-plus per year, propelling six to eight of them into the global top 50 medtech firms.

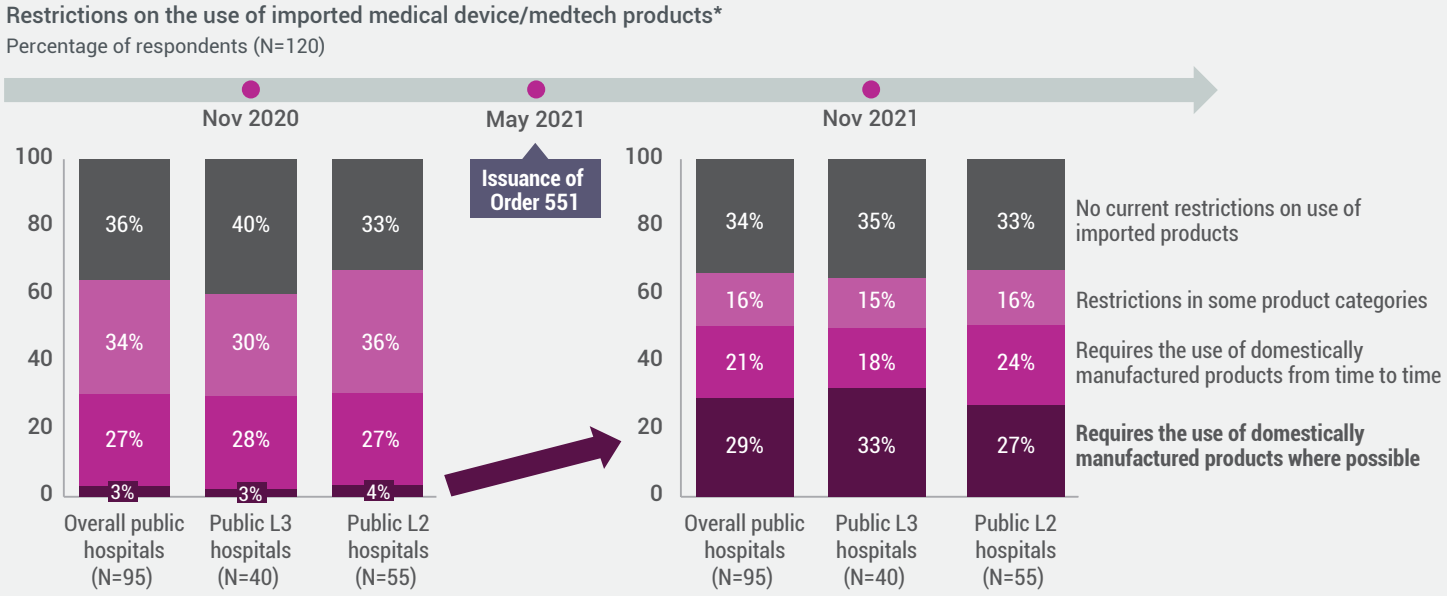
More narrowly, several National Medical Products Administration (NMPA) orders from 2020 and 2021 also carried this forward. For instance, *Order 104: Announcement on Matters Concerning the Production of Imported Medical Device Products*, from September 2020, provides an accelerated registration pathway for transferring from an import registration certificate to a local registration certificate of medical devices and IVDs.

We expect the combination of these policies and the overarching approach to create fierce competition from Chinese rivals for imported medtech products in the near future. Dealing with this regulatory and policy direction and the increased domestic competition that it will generate should be a high priority for MNCs in this space.

And, in fact, several MNC medtechs have recently ramped up their localization efforts in China. Among them are **Danaher** and **Siemens Healthineers**. Danaher invested more than $100 million in 2021 to establish a new diagnostics R&D and manufacturing base in Suzhou and, in 2022, it launched an upgraded China localization strategy to accelerate local

Figure 1

Before and After 551: Hospital Restrictions on the Use of Imported Medical Products



Note: *Survey question: *Which of the following statements best describes your hospital's attitude towards the use of imported medtech/medical device products? Wording for option provided was adjusted between 2021 and 2022 surveys.*

Source: L.E.K. 2021 and 2022 APAC Hospital Priorities Surveys

manufacturing and innovation with the aim of producing 80% of the products the company sells in China domestically.

Another case in point is Siemens Healthineers, which is moving forward with the localization of full product lines as one of three core pillars of Siemens's new China localization strategy unveiled in 2022. The company is putting considerable emphasis on this effort.

"The localization strategy is a critical measure for Siemens Healthineers to further integrate itself into China's new development landscape and achieve joint development goals with China," said Jerry Wang, president of Siemens Healthineers Greater China, in 2022.

Going Local

Going local in China is an easy to understand, but not always easy to implement, approach. Localization allows medtech manufacturers to meet patriotic procurement policies while also being included in policies that are favorable toward local companies.

Yet, the definition of what it means (and takes) to be local remains ambiguous and changes depending on the stakeholder.

For the medtech industry, gaining a local registration certificate from the NMPA is the minimum.

Throughout all the steps in the supply chain, L.E.K. Consulting has found that manufacturing a product domestically is key to its perceived "localness" among China's clinicians and administrators.

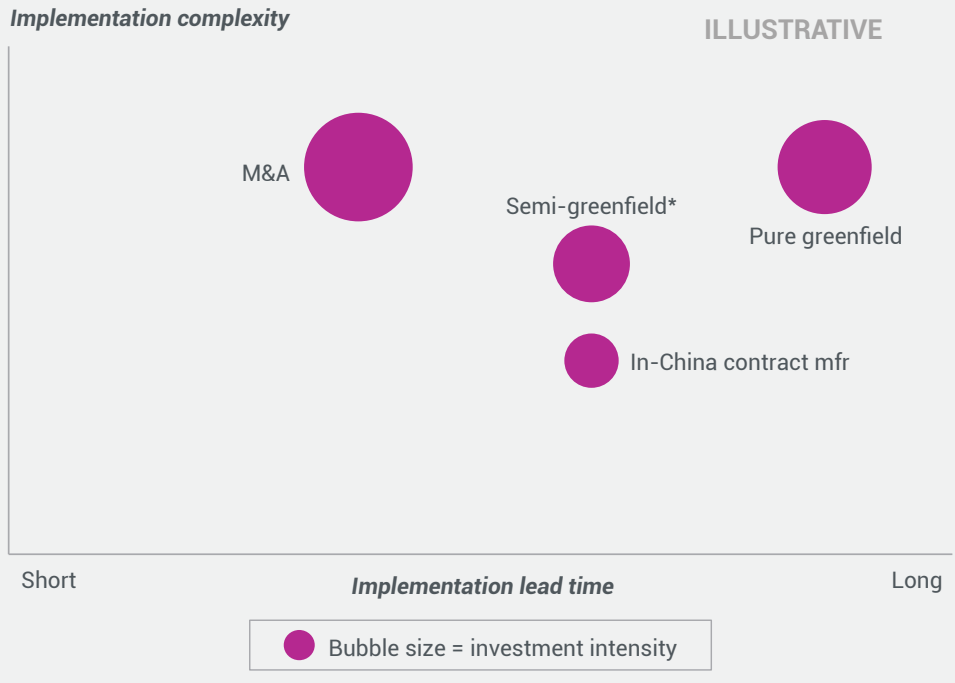
While NMPA's local registration policy explicitly lists "locally manufactured" (准字号注册证) in the definition, it does not specify the percentage of manufacturing or the number of manufacturing steps that have to be done in the country for it to be considered "Made in China."

This means there is some wiggle room for manufacturers to simply move final assembly, configuration, sterilization, or packaging to mainland China to qualify.

But interpretations can vary, and NMPA currently takes a case-by-case approach. L.E.K. Consulting predicts that the definitions may be revised in the future and become more sophisticated. For example, NMPA may add requirements tied to the percentage of domestic manufacturing or minimum levels of value added domestically for manufactured products.

Figure 2

Options for Localization—Eligible for 'Local' NMPA Certificate



Note: * *i.e., ready-made facility or extension to existing manufacturing footprint.*
Source: L.E.K. interviews and analysis

Which Products to Localize?

Right now, it seems logical for medtech manufacturers to move parts of their manufacturing processes to China to ensure continued access and competitiveness.

But L.E.K. Consulting advises corporations to think carefully when assessing and prioritizing portfolios for China localization, as it is not necessarily the optimal approach for all products, and it may not be needed for certain products. We regularly advise clients to look at their strategic position through this prism.

Medtech companies in particular need to consider localization through four specific dimensions, namely market dynamics, financial implications, operational complexity, and potential enterprise risks.

The first dimension focuses on market impact from localization. It weighs the implications on market size and future growth, competitive evolution, import substitution policies, and tendering constraints from the push to "go local." This dimension also considers the importance of lower-tier markets, as characterized by the city and hospital levels within China. Imported medical products can run into particular challenges in these markets. So, generally, localization efforts will have a greater impact for products that depend more on lower-tier markets.

The second dimension considers financial implications or simply put, the economics of it all. It considers how a shift to achieve Made in China status will affect a company's revenue in both the short and long term. And, subsequently, how it feeds into cost of goods sold for both the China and ex-China markets. Logistic cost considerations and possible tariff mitigations can also come into play.

Meanwhile, the depth of a company's operational complexity will impact its global supply chain capacity and even its product registration capabilities. There is also the capital expenditure to think about.

The fourth and final dimension is the enterprise risks. Though China's IP protection has improved considerably, there are unique challenges and risks with IP protection and technology transfers, which are required when going local.

Options to Achieve Made in China Status

Those that decide to push ahead with efforts to secure Made in China status have several options (*see Figure 2*).

With definitions still vague, companies have room to decide on the depth of manufacturing localization to employ and how it fits with their strategic plans.

Contract manufacturing through a local marketing authorization holder (MAH), joint ventures, M&A activities, and building from scratch (greenfield) are all viable approaches to China manufacturing localization. To help decide on a direction, companies should analyze case studies based on how other key players have utilized the different pathways.

Benefits

Achieving local status can generate numerous benefits for competitive medtech companies in China.

The first and most obvious is the ability to withstand and adapt to the country's ongoing regulatory changes, supporting continued access to the fastest growing market in the world and the ability to tap into its massive procurements.

The localization of operations is also great for supply chain optimization. Geopolitical tensions between China and the US raise the risk of sudden tariffs and import issues. Companies may want to hedge their bets operationally and financially.

The localization of a company's portfolio in China can also be meaningful clinically. With access to different patient pools and clinical practices, medtech manufacturers are able to test and tailor their solutions to fit a market that increasingly demands local data. (*See "Island Evidence: A Quicker Path to China's Market via Hainan Province?"* Market Pathways, *October 27, 2022.*)

Going local also provides access to a new pool of talent and innovation in China.

As made-in-China innovation becomes a stronger trend, having a foot in the door can mean better and faster entry to the ecosystem and its players. This, in turn, can lead to improved offerings by companies.

China also makes notable investments in promising domestic companies, which can translate into growth and enhanced commercial capabilities.

Manufacturing as a Possible Step

Eventually, MNC and foreign medtech companies aspiring to be key players in China's markets need to develop capabilities beyond commercialization, including in-China manufacturing, in-China supply chain, and in-China innovation.

Based on the direction the regulatory winds are blowing, manufacturing could be the first step that needs to be explored for companies to adapt to the world's fastest growing market for medical devices. Now's the time to consider your options.

About the authors

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