

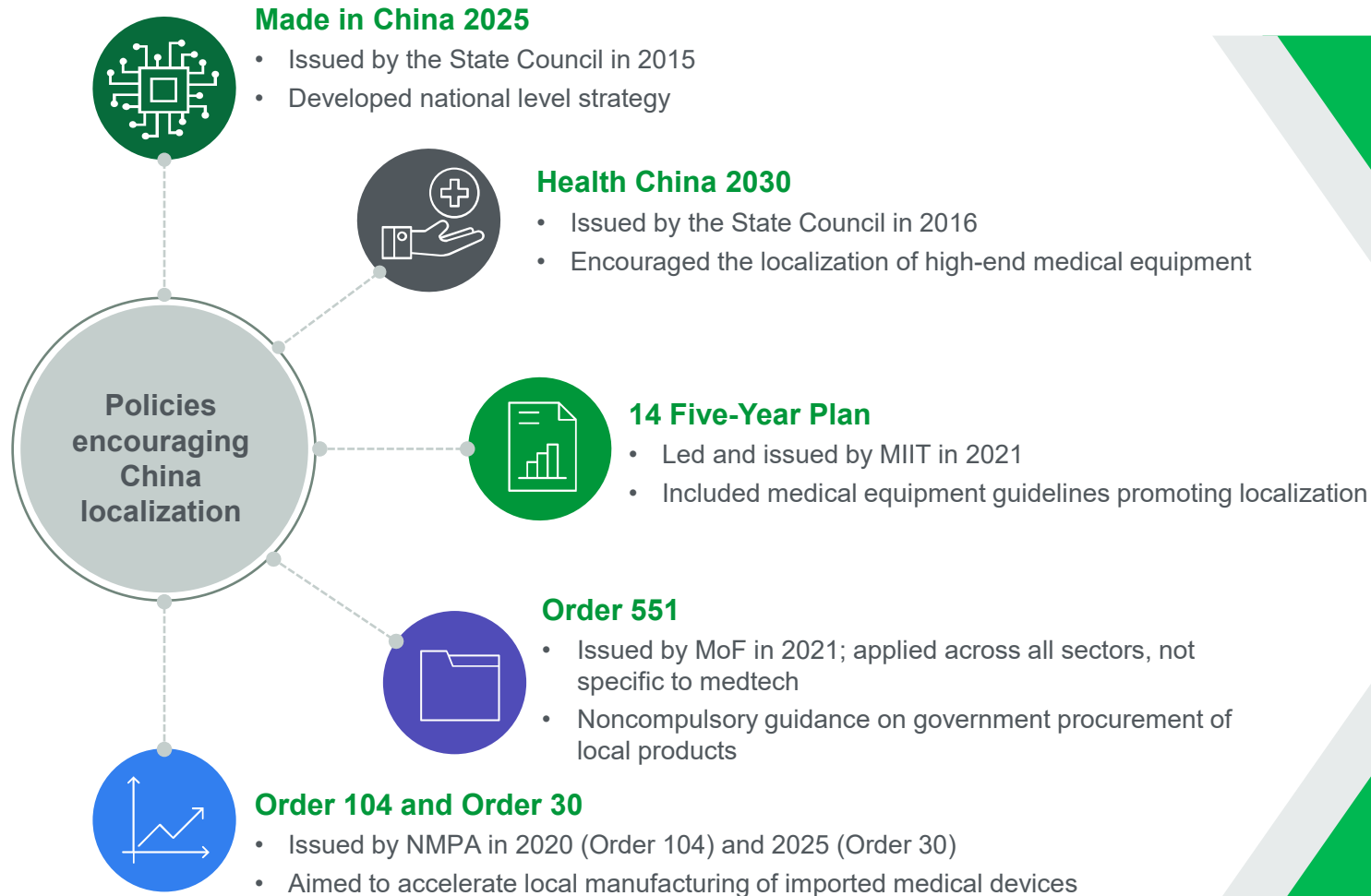
Progress With Ambiguity: China's Evolving Definition of Local Product in Medtech

August 2025

These materials are intended to supplement a discussion with L.E.K. Consulting. These perspectives will, therefore, only be meaningful to those in attendance. The contents of the materials are confidential and subject to obligations of non-disclosure. Your attention is drawn to the full disclaimer contained in this document.



There has been a broad set of policies encouraging medtech local manufacturing in China; however, the definition of a 'local' product has long lacked clarity



What is local ?

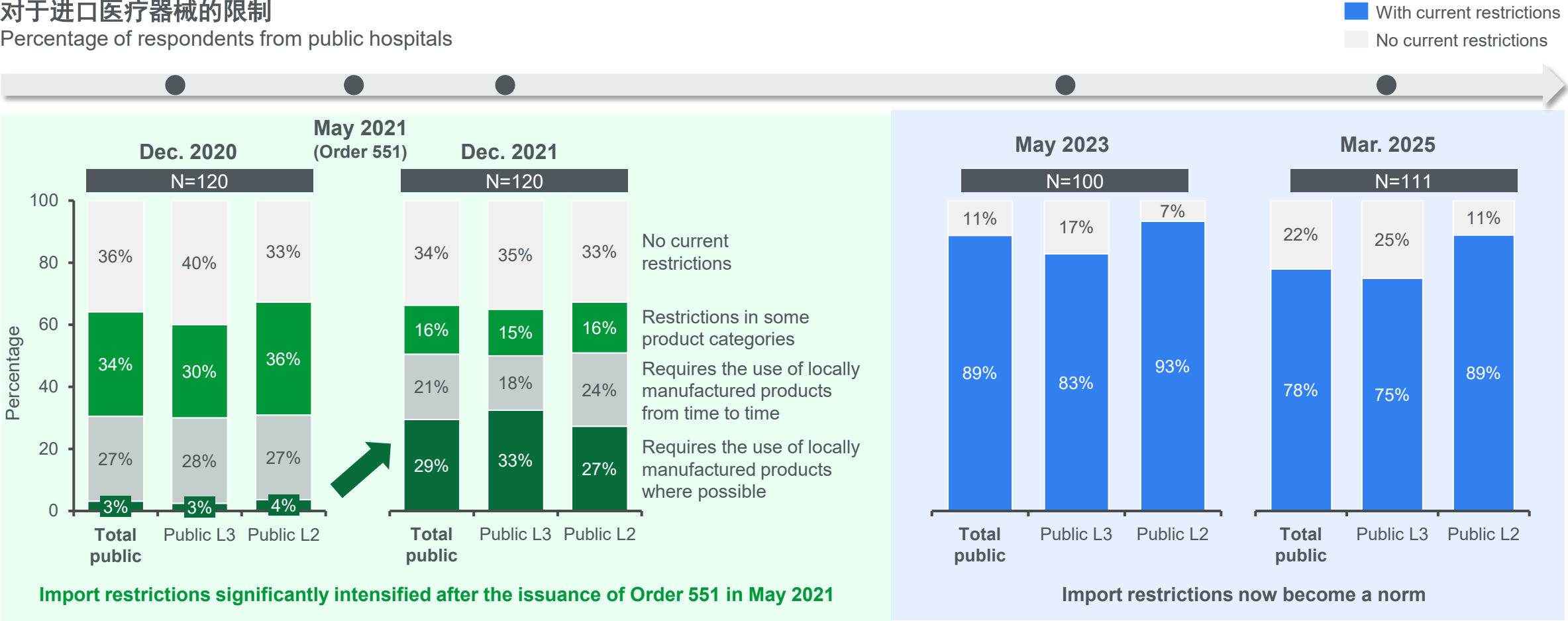
- There is no official written definition for local product
- The NMPA registration certificate is commonly used for defining a local product
- It requires at least final assembly to be completed within mainland China and case-by-case interpretation by NMPA

Note: MIIT=Ministry of Industry and Information Technology; MoF=Ministry of Finance; NMPA=National Medical Products Administration
Source: The State Council, MIIT, MoF, NMPA government website

The preference for local medtech products in hospital procurement has strengthened significantly post-Order 551 and has become a norm now

Restrictions on the use of imported medical device products*

对于进口医疗器械的限制
Percentage of respondents from public hospitals



Recent progress on local definition: China's Ministry of Finance issued a draft notice for public comment in December 2024, aiming to define and incentivize locally manufactured products



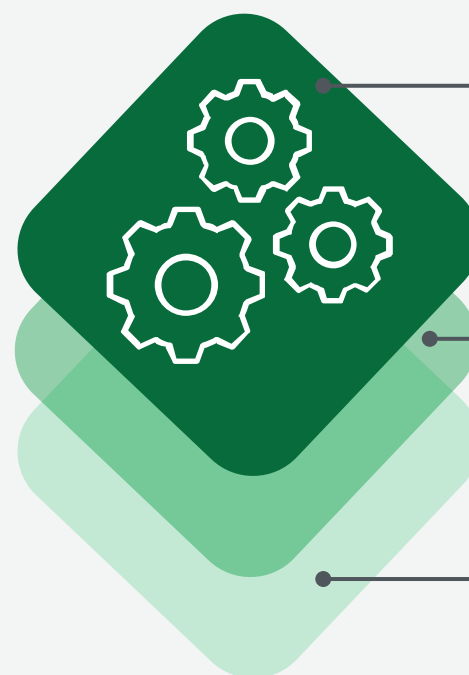
Notice on Standards and Implementation for Local Products in Government Procurement in China (Draft for Comments), issued by MoF, May 12, 2024

关于政府采购领域本国产品标准及实施政策有关事项的通知（征求意见稿）

- **Aims to address the ambiguities for identifying** local products
- **Incentivizes local manufacturing:** Local products receive a 20% price deduction advantage in tenders vs. nonlocal
- **Applies across all sectors:** This is a general policy not specific to medtech

Note: MoF =Ministry of Finance
Source: Ministry of Finance government website

Definition of Local products per the notice: three mandatory criteria



Substantive transformation

1 Must be made in China, with a substantial property transformation; labeling/packaging does not qualify

Minimum value-add

2 The percentage value of components produced in China must meet a defined threshold

Localize key components and steps

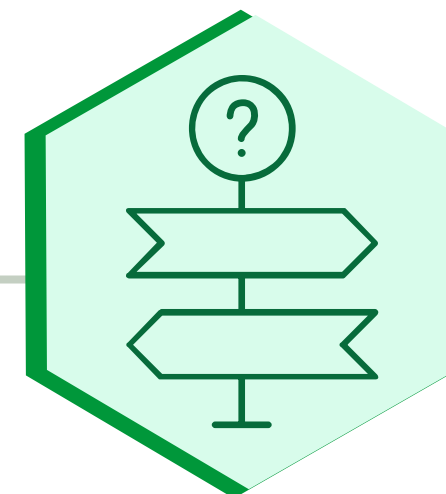
3 Key components and critical processes completed in China for designated products

Criteria 2 and 3 will be product-specific and refined over the next three to five years

Implementation of the notice may encounter various uncertainties and ambiguities, requiring further clarification and coordination efforts

Potential uncertainties and ambiguities of implementation of local product standards

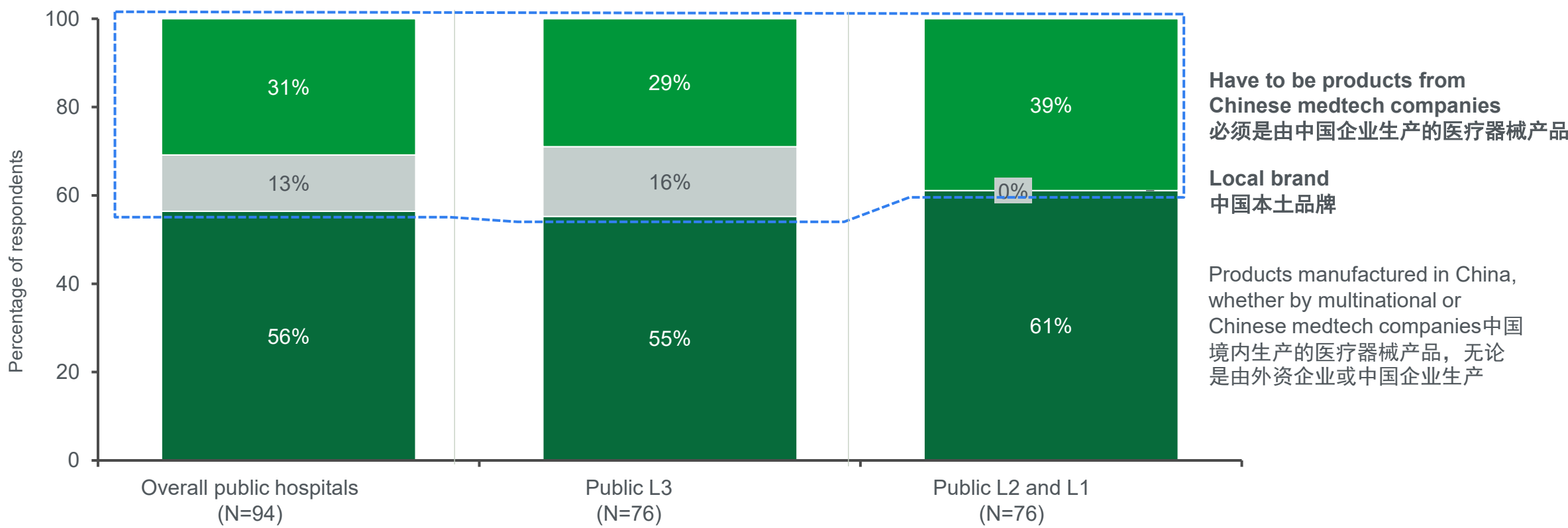
- ◆ **Value-add percentage difficult to define:** Varies significantly by industry and product; requires time and coordination to develop clear benchmarks
- ◆ **Definition of key components remains vague:** Lacks clear definitions and product scope, and importance differs across product categories, making enforcement challenging
- ◆ **Cross-authority coordination needed:** Effective implementation depends on alignment across multiple authorities (MoF, NMPA, MIIT, GACC)
- ◆ **Potential complexity with VBP:** The 20% price advantage for local products may clash with value-based procurement principles focused on lowest price
- ◆ **Unclear enforcement mechanisms:** Draft lacks details on monitoring, appeals and handling borderline cases



Note: MoF =Ministry of Finance; NMPA: National Medical Products Administration; MIIT =Ministry of Industry and Information Technology; GACC =General Administration of Customs of China;
VBP =Volume Based Procurement
Source:L.E.K. analysis

In the absence of a clear local definition, hospital-level interpretation varies, with some extending beyond manufacturing location and creating unintended barriers for MNC medtech companies

Definition of local product in medical device tendering*
招标采购中对“国产产品”的界定标准
Percentage of respondents



*Survey Question: How does your hospital define “domestic product” in medical device tendering? 在医疗器械/医疗设备招标采购过程中，您医院对于“国产产品”的界定标准是什么？
Source: L.E.K. 2025 APAC Hospital Priorities Survey

As China's definition for local medtech products continues to evolve, MNC medtechs need to deepen local value chain participation and enhance perceived local identity to navigate the uncertainties

Implications for MNC medtechs

- 1 Definition of local may evolve beyond final assembly**
Companies should not rely on last-step assembly as a sufficient localization strategy in the long term
- 2 Prepare for tightening procurement dynamics**
Long-standing hospital preference for local products and increasing import restrictions may affect key portfolio performance
- 3 Engage early in shaping future standards / policies**
Proactively engage with authorities and industry associations to provide input into how key criteria are defined and enforced
- 4 Evaluate the benefits and necessity of localization to succeed in China**
Assess the trade-offs across market access, product competitiveness and investment/economics to determine whether localization is needed
- 5 Integrate China localization into your global manufacturing and supply chain considerations**
Continuous policy momentum suggests local production, sourcing or partnerships should be part of global footprint planning
- 6 Localization is not just compliance — it could be a competitive differentiator**
Local manufacturing may improve lead times, cost efficiency, and stakeholder engagement, driving competitive advantage in China
- 7 Consider enhancing your "Chinese identity" through local partnerships**
Strategic partnerships, joint ventures or acquisitions with Chinese medtech may strengthen perception and support broader access



Note: MNC =Multinational Corporation
Source: L.E.K. analysis

L.E.K. could help you navigate your China localization strategy and translate it into actionable initiatives and competitive advantage

What L.E.K. can support



Strategic positioning and policy navigation

- What is the right China localization strategy for our business?
- What localization approaches are competitors pursuing? What lessons can we learn?
- Which parts of our portfolio should be prioritized for localization?
- What are the latest policy developments impacting localization, and how might they evolve?



Commercial and operating model

- How do hospitals interpret local in practice, and how should we adapt regionally?
- What are the practical options for achieving localization in China?
- How can we prepare for policy uncertainty, evolving criteria and potential enforcement challenges?
- What are the key benefits and risks associated with localizing in China?



Policy shaping and engagement

- What opportunities exist to shape a more favorable localization policy environment?
- Who are the critical stakeholders we need to engage with, and how?
- Can we develop an evidence-based white paper to support our policy engagement?
- What targeted messaging and proof points will make our engagement more effective?

We are thought leaders in medtech and healthcare

Selected L.E.K. insights

EXECUTIVE INSIGHTS
Going Local: Strategic Considerations for Medtech Manufacturers in China

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 and favor local products. This will have significant impacts on who will need to adapt to ensure they maintain market access.

Regulators in Mainland China have adapted consideration by MNC medtech manufacturers.

A recent case in point is Order 551: Guideline Products launched by the Ministry of Finance Technology in May 2021. Known as the 'Buy China' procurement budget for 215 local products creates market access barriers for foreign segments of China's medtech market.

L.E.K. Consulting's survey of hospitals in China implemented Order 551 or planned to do so were not likely to implement the order and months after Order 551 was issued, the number of medtech products where possible jumped.

Before and After 551: Hospital's Actions to Restrict the use of imported medical devices/healthcare products
Percentage of respondents (N=102)

Note: "Survey question: Which of the following statements best describes your hospital's approach to restricting the use of imported medical devices/healthcare products?"
Source: L.E.K. 2021 and 2022 APAC Hospital Priorities Survey

2

EXECUTIVE INSIGHTS
Unlocking Future Growth: APAC Medtech Outlook 2025

Figure 1
APAC medtech market size (ex-mfr. price)
USD Billions

Note: APAC=Asia Pacific; IVD=in vitro diagnostics
Source: Statista 2024, L.E.K. analysis

Regional powerhouses and emerging markets

China remains a compelling market with despite ongoing challenges. As the second largest market, it accounts for approximately 20% of the global population and almost all diseases and disease states, amounting to more than 210 million people.

China is already the second largest medtech market in the world and has the largest patient pool for many diseases globally. Growth of China's medtech market is expected 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

1

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The Asia-Pacific (APAC) region, home to approximately 60% of the global population and accounting for about 30% of global medical technology spending, represents a critical landscape for the future of medtech. As a dynamic collection of markets, APAC is characterized by rapidly evolving strategic issues, including regulatory changes, technological advancements and shifting healthcare demands driven by demographic trends. The increasing emphasis on personalized healthcare solutions and digital innovations further complicates the competitive environment. Given these factors, this paper sets out the key issues L.E.K. Consulting believes is essential for any medtech company with ambitions for the region in 2025.

Expanding horizons: APAC medtech's projected growth in 2025

The APAC region presents a diverse array of markets, ranging from nascent to highly developed. By 2025, the value of the APAC medtech industry was estimated at approximately \$121 billion (at ex-manufacturer prices), with projections indicating a compound annual growth rate of 5%, reaching approximately \$140 billion by 2025 (see Figure 1). The medical device market has experienced steady overall growth. However, the in vitro diagnostics (IVD) market's return to pre-pandemic growth patterns, following the surge during COVID-19, resulted in a slight decline in 2023.

APAC's medtech market is being influenced by rising demand for advanced and personalized medical technologies, driven by trends such as telemedicine and precision medicine. Economic growth across the region, increasing prevalence of chronic diseases and market access/affordability improvements are all key factors contributing to the evolving medtech ecosystem in APAC. Local dynamics, including China's emphasis on domestic innovation and Japan's aging population, are further fueling the expansion of the market.

2

Both public and private hospitals are more positive about the future budget/profitability outlook compared to what was observed in prior surveys

Public hospital budget outlook for the next three years (China*)
公立医院未来3年预算展望 - 中国
Percentage of respondents

Private hospital profitability/ROI for the next three years (China**)
私立医院未来3年盈利能力展望 - 中国
Percentage of respondents

L.E.K. sponsors a unique analysis of hospital priorities in APAC; the 2025 study was executed during February and March, and engaged 111 hospital executives in China across public and private providers

L.E.K. APAC Hospital Priorities Survey respondent mix
L.E.K. 亚太地区医院调研参与方组成
Percentage of respondents

China respondent mix
中国调研参与方组成
Percentage of respondents (N=111)

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Hospital Priorities 2025

China Edition: Key Findings for Medtech and Pharma Companies

June 2025

[Going Local: Strategic Considerations for Medtech Manufacturers in China](#)

[Unlocking Future Growth: APAC Medtech Outlook 2025](#)

[Hospital Priorities 2025 China Edition: Key Findings for Medtech and Pharma Companies](#)

More market-leading insights and thought leadership available on the L.E.K. website: <https://www.lek.com/insights>

Reference

Relevant policies and regulations

中国制造2025

健康中国2030

“十四五” 医疗装备产业发展规划

国家药监局关于进口医疗器械产品在中国境内企业生产有关事项的公告（2020年第104号公告）

国家药监局关于进一步调整和优化进口医疗器械产品在中国境内企业生产有关事项的公告（2025年第30号公告）

关于政府采购领域本国产品标准及实施政策有关事项的通知（征求意见稿）

Connect with us



Helen Chen

Greater China Managing Partner, Global
Sector Co-Head, Healthcare and Life Sciences

✉ h.chen@lek.com



Stephen Sunderland

Partner, APAC Regional Head, Healthcare
and Life Sciences

✉ s.sunderland@lek.com



Grace Wang

Partner, Healthcare and Life Sciences

✉ g.wang@lek.com



Andrew Fa

Principal, Healthcare and Life Sciences

✉ a.fa@lek.com

