



**Two-Invoice Policy:
A Paradigm Shift in China's
Medical Devices Industry**

The two-invoice policy and its impact on China's medical devices industry

Since April 2016, provincial governments have begun to release implementation policies and guidance documents in response to the two-invoice requirement promulgated by the central government. With the rollout of the two-invoice policy, besides the tax consideration, the government aims to consolidate the fragmented distributor market for pharmaceuticals and medical devices with the goal of increasing overall distribution chain transparency, developing an environment in which distributors' markups and potential fraudulent behaviors can be better controlled, and making it easier eventually to lower the overall prices that patients have to pay for medical devices.

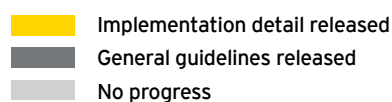
Following the policy roll-out for pharma, one can expect this will pose similar impacts on MedTech stakeholders

Figure 1. China's Two-Invoice Roll-out Timeline for the Pharma Industry

April 2016



Before the policy launch, Fujian was the only province that had fully implemented the two-invoice policy. No other province had published an agenda to follow.



August 2017



By August 2017, nineteen provinces, including Shaanxi, Ningxia, Qinghai, Sichuan, Hunan, Anhui, Fujian, Guizhou and Hainan, as well as Chongqing, had released implementation details with timelines and nine others had published general guidelines.

A gradual roll-out that is expected to pick up pace

If we take hints from the roll-out of the two-invoice policy in the pharmaceutical industry, it is likely that the nationwide implementation for medical devices will also follow a "pilot and replicate" model, meaning initial roll-outs will start with a few provinces and key cities in those provinces and then be quickly replicated by other provinces. We feel that the implementation time-frame will be longer than that of the pharmaceutical industry due to the sheer number of different products that are classified as medical devices and the fact that the distribution models for products are much more complicated. We expect the initial roll-out to start with high-value consumables, followed by in vitro diagnostic devices (IVD) and then low-value consumables.

| The road ahead for medical devices players

The implementation of the two-invoice policy will entail significant impacts on medical device players compared with pharmaceutical players due to the higher margin profile for the different value-added service roles that distributors play.

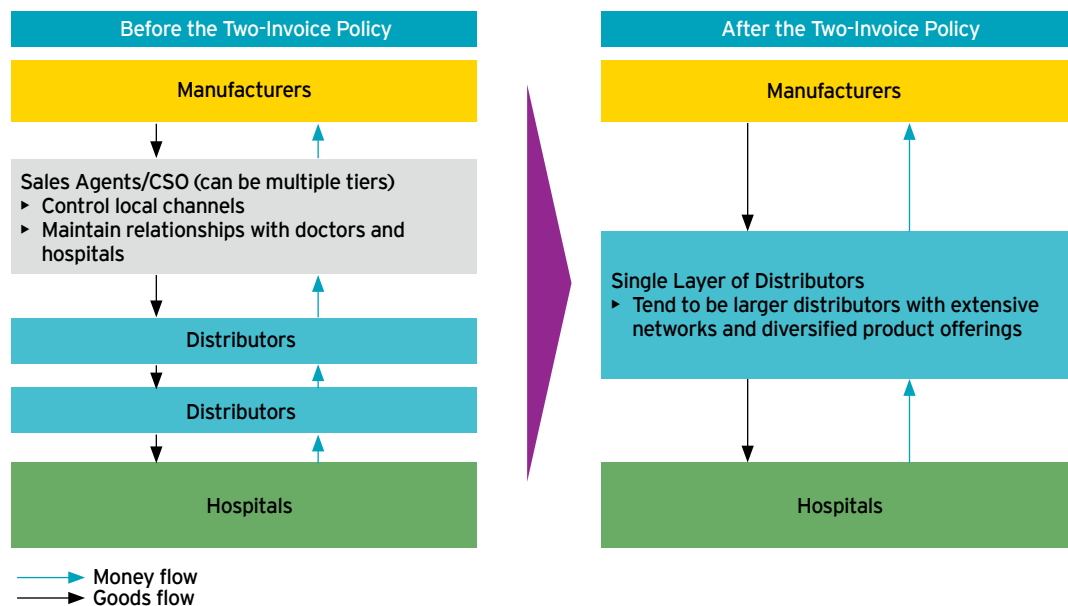
For manufacturers, the two-invoice policy means that they will only be allowed to utilize one layer of distributors to deliver to hospitals (one invoice from the manufacturer to the distributor and a second invoice from the distributor to the hospital) as opposed to the current multilayer model. The limitation for utilizing multiple layers of distributors may mean risks in terms of loss of account and geographic regional coverage, which in turn could mean significant top-line risks for manufacturers that are ill-prepared for the changes. The reshuffling caused by the policy rollout will mean the cooperative models with the current tier 1 and tier 2 distributors will drastically change; some of the distributors may have to be converted to contract sales organizations (CSO), which means renegotiating cooperative and partnership details including the allocation of promotional expenses, roles and responsibilities, ownership of goods, etc. All of these factors point towards significant challenges in terms of operational and compliance risks that manufacturers need to be aware of and prepared for.

On the other hand, a slew of challenges lie ahead for medical device distributors as well. We foresee a significant trend towards market consolidation, with larger leading distributors looking to acquire strong regional players to build up their account and regional coverage. This will mean significant disruption in the market, which will go through a phase of restructuring and renegotiations with manufacturers. Smaller distributors that do not have strong regional coverage need to quickly transform themselves or be squeezed out of the market by the consolidating competition.

Separately, we also foresee new competitors in the form of pharmaceutical distributors, like Sinopharm, quickly entering the device distribution market. These massive pharmaceutical distribution players have built up strong hospital account coverage and can quickly adapt their models for devices as well. All in all, a reshuffling and restructuring of the medical device distribution market is imminent to comply with the new regulatory environment, and we foresee drastic changes in the form of market consolidation, reorganization of distributors and overall changes in the collaboration models between manufacturers and distributors.

| The two-invoice policy will compress the distribution value chain into one single layer

Figure 2. The Two-Invoice Policy's Impact on the Distribution Value Chain



Current medical devices distribution model and potential options in the future

The medical device industry currently can be broken down into four different segments, including: **low-value consumables** (needles, syringes, etc.), **high-value consumables** (cardiovascular and orthopedic implants, etc.), **in-vitro diagnostics** (diagnostic equipment and reagents), and **large medical equipment** (imaging equipment, etc.) Each of the four categories has a unique business model, and therefore unique characteristics in its respective distribution channels. Consumables and reagents distribution channels mainly rely on various levels of distributors (tier 1 and tier 2, and some products may need to be distributed to county-level hospitals in rural areas and need even lower-tier distributors) who control the last-mile connection to the hospitals and are currently highly fragmented and widely dispersed across the nation.

Medical devices can be segmented into four major categories requiring different distributors

Product segments	Business model	Distributor landscape	Channel development trends	Required core competencies for distributors
Low-Value Consumables	<ul style="list-style-type: none"> Wide geographic and account coverage 	<ul style="list-style-type: none"> Rely heavily on tier 1 to tier 3 distributors Highly fragmented market 	<ul style="list-style-type: none"> Channels will continue to expand to reach more lower-tier cities Cross-regional distribution platform being developed 	<ul style="list-style-type: none"> Wide geographic and account coverage and efficient delivery network Strong connection with hospitals and ability to control costs

Low-Value Consumables: Due to the low differentiation between competing products and brands, it is important to continue increasing the number of distributors and expanding coverage area to ensure continued growth. Regional and hospital coverage, efficient distribution network, and control of hospital accounts are distributors' core competencies and key differentiators. There is an emerging trend to develop a new cross-regional distribution platform driven by medical device manufacturers' needs which will begin to eat into traditional distributors' market share. At the same time, manufacturers are continuing to expand their geographic coverage and extend their distributor channels to lower-tier cities.

High-Value Consumables	<ul style="list-style-type: none"> Differentiated product delivery services and professional clinical services 	<ul style="list-style-type: none"> Rely heavily on tier 1 to tier 3 distributors Highly fragmented market 	<ul style="list-style-type: none"> Increasing demand for higher working capital Centralized distribution platform increasingly in demand 	<ul style="list-style-type: none"> Strong working capital to handle inventory Professional capabilities to provide clinical services
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High-Value Consumables: Distributors in this category often need to provide follow-up services for surgical equipment and be on standby for just-in-time delivery services. Due to inventory requirements, distributors will need to have ample working capital and be able to provide professional clinical services as well. The need for a central distribution and delivery platform is mainly driven by the growing need for a stronger working capital base mainly due to growth from orthopedics and cardiovascular treatment areas; but as of now, the competency and capabilities of the platform service providers are still lacking.

Product segments	Business model	Distributor landscape	Channel development trends	Required core competencies for distributors
In-Vitro Diagnostics	<ul style="list-style-type: none"> Place equipment in hospitals for free and earn higher margins with reagents 	<ul style="list-style-type: none"> Rely heavily on tier 1 to tier 3 distributors Highly fragmented market 	<ul style="list-style-type: none"> No drastic changes foreseen in the short term 	<ul style="list-style-type: none"> Strong connection with hospitals Ability to service diagnostics departments Cold chain capabilities

In-Vitro Diagnostics: Large distributors in general acquire equipment from manufacturers at low cost and place the equipment in hospitals' diagnostics arms to drive usage and therefore sales of high-margin testing reagents. Manufacturers look for distributors to have hospital connection capabilities, after-sales support capabilities (equipment maintenance and repair, software training, reagent distribution) and cold chain storage and transportation capabilities. The distribution market for IVD products is predicted to remain relatively stable in the near future.

Large-Scale Equipment	<ul style="list-style-type: none"> Equipment leasing 	<ul style="list-style-type: none"> Rely heavily on tier 1 distributors 	<ul style="list-style-type: none"> Expand business into equipment maintenance and repair for higher margins 	<ul style="list-style-type: none"> Strong working capital Strong connection with hospitals Maintenance and repair capabilities
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Large-Scale Equipment: A direct sales model for high margin products is adopted for selected key account areas, complemented by a distributor model (usually 1 layer, at most 2) in areas where the manufacturers have limited resources to approach or serve clients directly. Distributors often have to help smaller clients on leasing plans to lower their financial barriers. Some large distributors have been trying to build up their maintenance and repair capabilities in recent years to expand and deepen their connections with hospitals, attract manufacturers without local after-sales service capabilities, and improve their profitability. The large-scale equipment segment may not be significantly impacted by the two-invoice policy in near future and the distribution model is predicted to remain relatively stable as well.

Transformation journey for manufacturers and distributors under the new policy

Under the two-invoice policy, consumable and reagent manufacturers will inevitably go through business model transformations. The necessary changes are far reaching and will not only impact distribution channels, but also entail significant changes in the distributor selection process, pricing, tax and financial and compliance areas as well. Manufacturers and distributors need to be able to take a step back and have a holistic understanding of the market dynamics and adjust their strategies accordingly.

For distributors and wholesalers, tier 1 players and larger regional wholesalers will continue to expand their channel networks to cover more hospitals. For tier 2 and below distributors, there are many potential transformative paths including: elevating to become tier 1 distributors, being acquired by tier 1 distributors, and adjusting their business model to become contract sales organizations or logistics providers.

In the transformation process, manufacturers must develop new relationships with the shuffling pool of distributors and seek to partner with the most appropriate players based on product characteristics, target market and account locations, cost model and other pertinent considerations. On the other hand, distributors need to plan strategically based on their capabilities and core competencies and renegotiate with manufacturers regarding their new roles and responsibilities. Due to the changing market dynamics, this transformative process will mean a significant reshuffling in the relationships and dynamics between manufacturers and distributors.

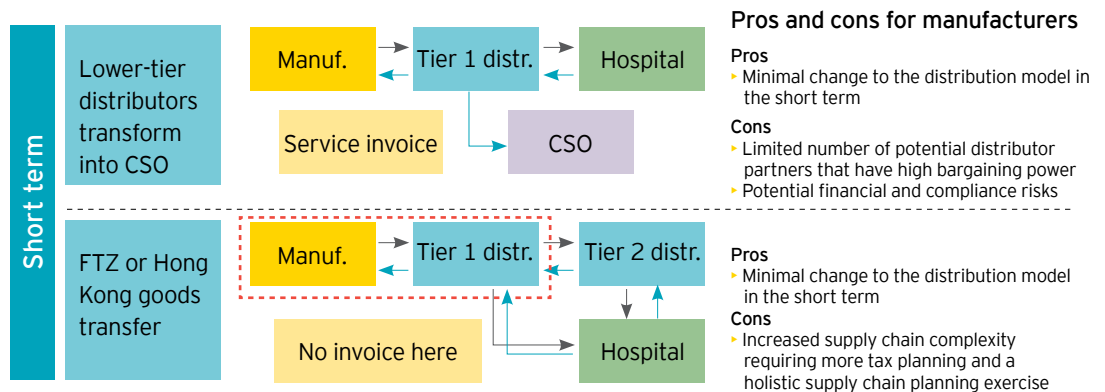
Manufacturer's transformation

Distribution model: During the design and implementation of the new distribution models under the two-invoice policy, manufacturers need to consider internal capabilities along with their short-, medium- and long-term needs. We believe there are many potential operating models that can work under the policy and have chosen a few representative models for reference.

Short-term "quick wins" with minimal operational impact:

- Renegotiate with distributors and turn them into contract sales service providers:** Distributors will no longer rely solely on product sales margin as the key source of income but many may need to become service providers and charge servicing fees instead. This model will be the fastest in terms of transformative timeline with minimal impact on the overall distribution channel, but may have to address the risks on margins and pricing, overall finance operations and potential compliance.
- Utilizing free trade zone (FTZ) or offshore transfer of goods:** This model requires the manufacturer and first-tier distributor to have entities either in one of China's free trade zones or offshore locations (Hong Kong for example). The products can be sold between the two entities in the FTZ or offshore, thereby eliminating the invoice required if the transaction was performed onshore in China. The tier 1 distributors can then sell to a second-tier distributor within China. This model would have a minimal impact on the channel but would have other hurdles to overcome including figuring out a way to book offshore international revenues, transfer pricing for the distributors, and the related tax and compliance risks.

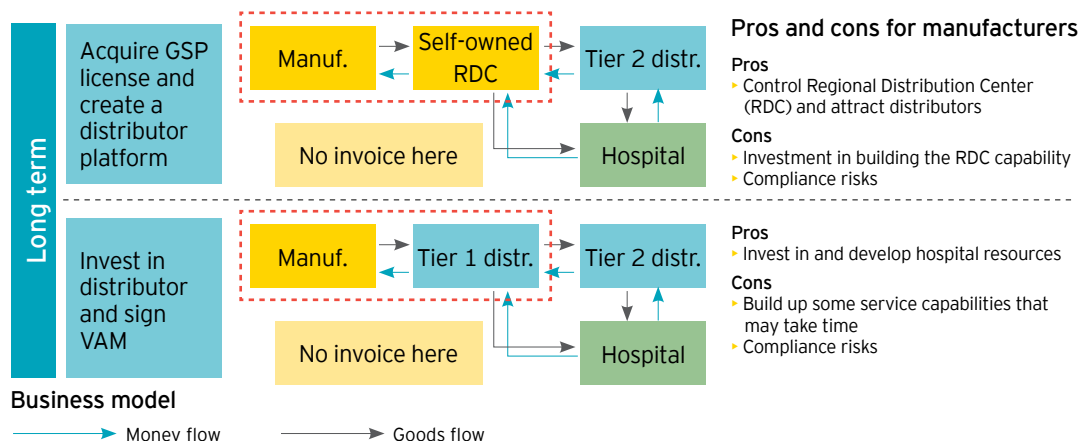
Figure 3. Potential Business Models Catering to Short-term Needs



Longer-term transformation requiring larger operational changes:

- Acquire or apply a license to self-operate the distribution platform:** Companies can acquire or apply the GSP licenses to establish regional distribution platforms and replace the need for a first-tier distributor. This model requires strong operational capabilities to establish an in-house team to operate the distribution platform. The company will need to account for the potential compliance risks as well.
- Invest in distributors and sign valuation adjustment mechanism (VAM) agreement:** Manufacturers can potentially consider investing in distributors to have better control on hospital accounts and utilize VAMs to guaranty mutual beneficial relationships. This model will mean a certain amount of financial and compliance risks to bear as well.

Figure 4. Potential Business Models Catering to Long-term Needs



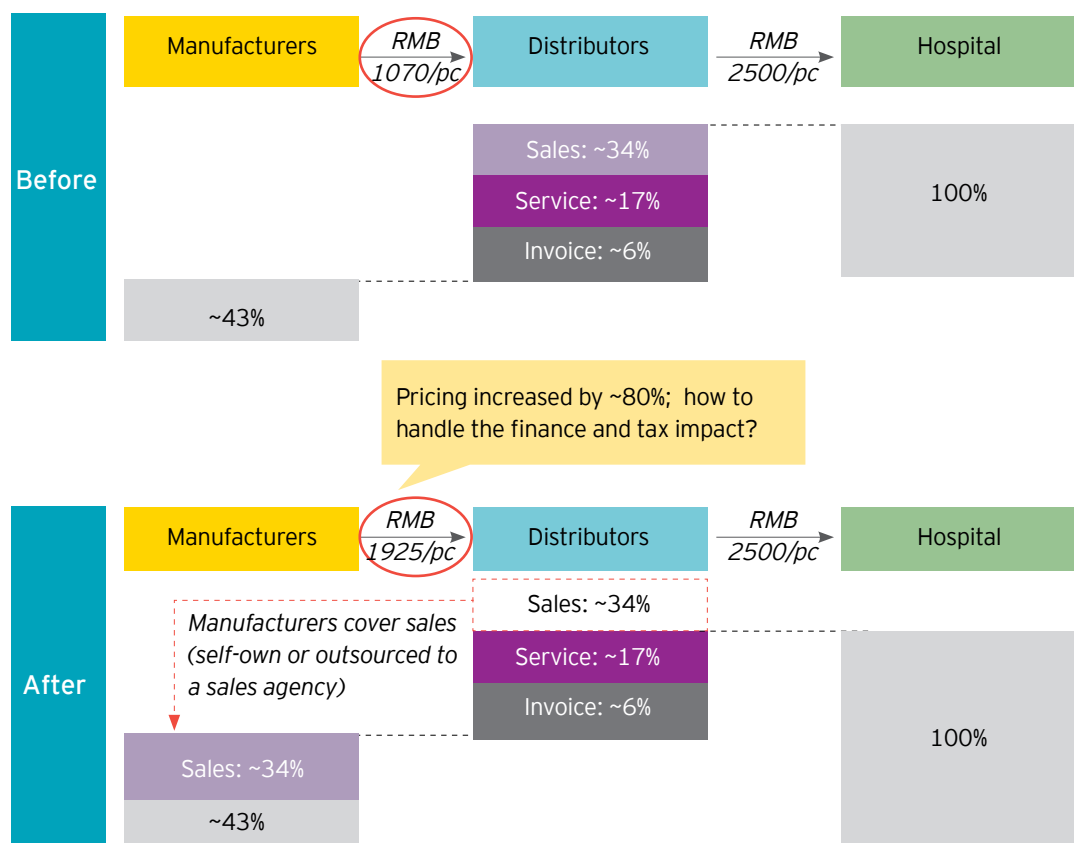
Reshuffling distributor tiering and selection: Through this transformative process, it is inevitable that distributors will go through a round of reshuffling. Manufacturers need to systematically and carefully select the right distribution partners and take into consideration the competitive environment and existing partnership relationships. We believe there are three types of distributors that can potentially become the future sole tier of distribution partners with manufacturers.

1. **Current tier 1 distributors that have a wide coverage and control of point of sales:** These distributors already have a sizeable coverage area and can potentially expand their geographic coverage through acquisitions of lower-tier distribution partners. These distributors can help manufacturers quickly expand their account and regional coverage and have strong bargaining power for price negotiations. Examples of such companies include Sinopharma, Shanghai Pharma and Jointown.
2. **Original tier 2 and tier 3 distributors that will be elevated to tier 1:** These distributors already have strong regional coverage in their respective provinces and cities with strong connections with regional hospitals. These players can potentially expand their coverage and working capital and renegotiate with manufacturers to become tier 1 distributors. These players may be quite willing to partner with manufacturers due to the potential increase in margins through a transformation.
3. **Hospital-appointed distributors:** Original tier 2 and tier 3 distributors who own operational rights through public-private partnerships with hospitals to hospitals and hospital groups. These players often bear inventory on behalf of the hospitals and have strong relationships with these selected hospitals.

Pricing, tax and financial impact: The new business models will entail a reshuffling of the roles and responsibilities between manufacturers and distributors. Manufacturers need to reevaluate their cost and profitability models and develop new operating models that are aligned with their strategies and goals. The tax and financial operational impact will need to be considered as well.

It is important to prepare for tax/finance concerns related to pricing change due to business model change

Figure 5. Pricing Change Due to Business Model Change, Hip Replacement Implant as an Example



Investment opportunities under the two-invoice policy

Under the two-invoice policy, we foresee two trends that will drive a paradigm shift in the medical devices market and will also create potential investment opportunities:

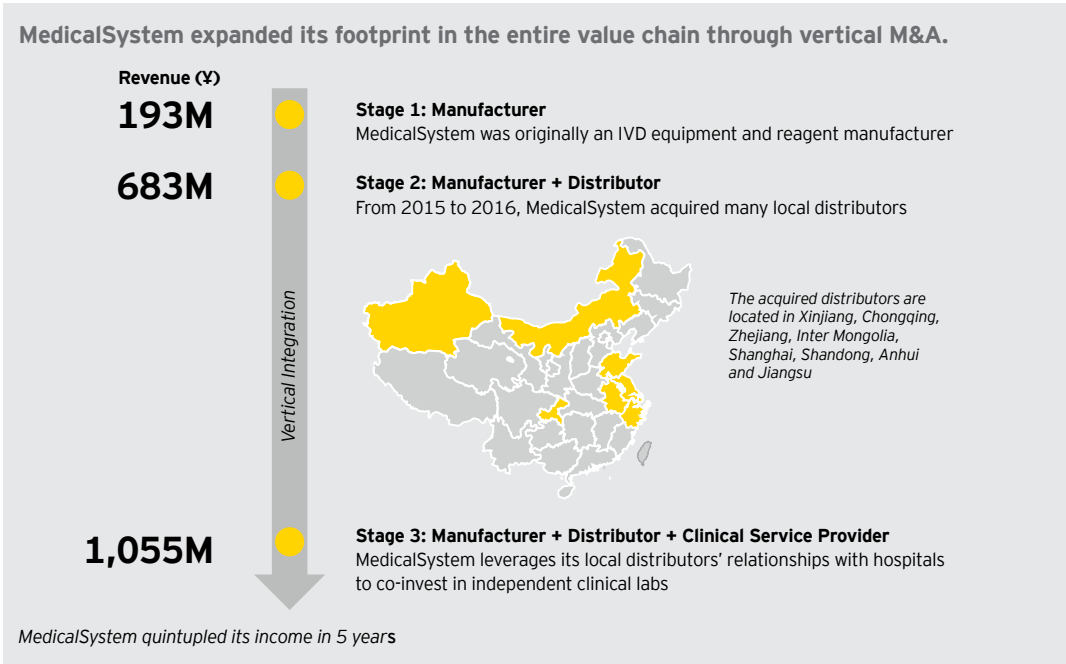
Vertical integration

The restrictions that the two-invoice policy places on manufacturers, and the multitiered distributor system means that many of the manufacturers who have capital and operational capabilities may start exploring opportunities for vertical integration or acquisition of distributors to build their own in-house distribution network to eliminate the many layers of distributors the devices have to pass through and the corresponding invoices between the intermediaries.

Case Study 1: MedicalSystem Biotechnology Co., Ltd. (MBC) is an in vitro diagnostics manufacturer based in Eastern China and is publically listed on the Shenzhen Stock Exchange. In 2015, MBC started its plan to vertically integrate and acquire key regional distribution partners to secure its distribution channel to important hospital accounts. Between 2015-2016, the company made multiple acquisitions of distributors across eight different provinces, successfully expanding its geographic coverage. The company enjoyed a stellar year, growing at 55% year on year from 2015-2016, which was a much faster pace than previous years.

MedicalSystem’s vertical integration efforts expanded its market presence and helped it achieve stellar growth

Figure 6. Medicalsystem’s Vertical Integration History



Horizontal integration

Medical device distributors that have scale and good geographic coverage across different regions may begin exploring acquiring other distributors to expand their geographic and hospital account coverage. Existing first-tier distributors may acquire other distributors to solidify their positions and have more bargaining power when negotiating with manufacturers, while smaller or lower-tier distributors may want to acquire other players to expand coverage and scale up to become future first-tier distributors.

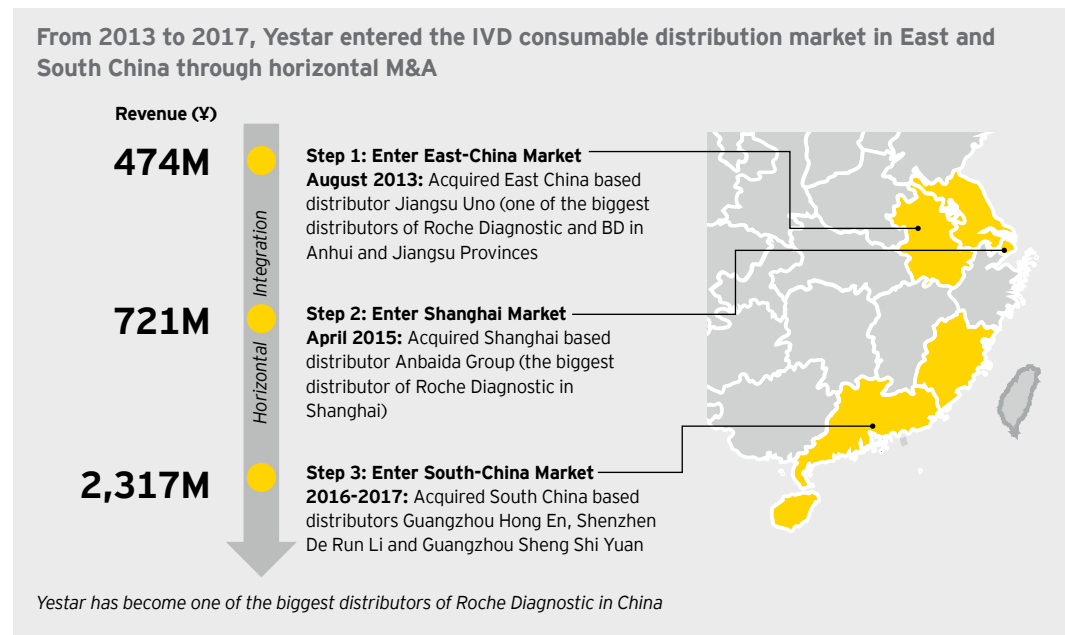
Case Study 2: Yestar Healthcare Holdings Co. Ltd. (Yestar) was a relatively small regional distributor of medical equipment based in the Shanghai area. Starting in 2013, Yestar began large-scale acquisitions of South China-based distributors of IVD products, including Guangzhou Hong En, Shenzhen De Run Li, and Guangzhou Sheng Shi Yuan, significantly expanding Yestar's geographic coverage of the market. The horizontal integration helped Yestar quintuple its revenues from RMB 474m in 2013 to RMB 2,317m in 2016. Yestar is now the largest China distributor of Roche Diagnostics, the market's largest IVD device manufacturer, and is quickly expanding its portfolio to cover medical imaging devices as well.

Yestar expanded its IVD consumable distribution business in East and South China by acquiring local distributors

Yestar expanded its distribution network through horizontal M&A.

Before entering the IVD consumable distribution market, Yestar's medical business was focused on medical radiology film manufacturing and distribution in China.

Figure 7. Horizontal M&A History of Yestar's Distribution Business





Closing

The roll-out of the two-invoice policy will undoubtedly impact the health care and medical devices landscape significantly in the next few years. Device manufacturers and distributors will inevitably go through drastic transformations to adapt to the coming changes. The following are our recommendations for each of the players in the value chain.

Manufacturers: Players should think more strategically and upgrade business models to restructure their distribution model, look for appropriate partners in distribution channels, renegotiate appropriate pricing, and ultimately work towards improving overall operational efficiency and business performance. It may be wise to select one or two provinces as pilot sites to test new operating models and make adjustments and replicate workable business models to other regions.

Distributors: The two-invoice policy is an opportunity for leading and capable players to stand out in the market. Players should leverage existing capabilities and resources and expand coverage in terms of accounts and geographic regions. They should also reach out to manufacturers and renegotiate and/or transform into a contract sales organization or logistics partner to gain market share in selected market segments.

Investors: Potential vertical and horizontal integration will lead to a large-scale consolidation. Significant investment opportunities will continuously appear during this process. Investors should focus on leading manufacturers and distributors that have the potential to become industry leaders with strong capabilities and coverage of hospital accounts.

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