

# Dilemmas Encountered by Small and Medium-sized Orthopedic Medical Device Manufacturing Companies in Healthcare Reform Based on a Supply Chain Perspective: Taking a Manufacturer in Jiangsu Province as an Example

Wanting Ye\*

School of Politics and Public Administration, Soochow University, Soochow, China

\*Corresponding author: 2002409045@stu.suda.edu.cn

**Abstract.** As China's healthcare reform progresses, the medical device industry is receiving significant attention as an essential part of the healthcare delivery system. Current research on the supply and management of medical devices in the context of healthcare reform mainly focuses on the downstream of the supply chain to innovate the management model of orthopedic consumables in hospitals and realize competent healthcare. However, only a few studies have focused on medical device manufacturers upstream of the supply chain and proposed measures to improve supply chain performance. This paper takes a medium-sized customer medical device manufacturer in China as a case study. This study analyzes the problems revealed in its supply chain operation through literature research, case study analysis, and fieldwork. It proposes countermeasures for the continuous improvement of the industry against the background of healthcare reform. The study found that small and medium-sized medical device manufacturers were not using management information systems adequately and were suffering from the impact of healthcare reform by sticking to their old distribution models. For long-term growth, these small and medium-sized medical companies should focus on research and development, cater to market needs, integrate downstream distributors, and work with hospitals to establish a more transparent and efficient healthcare supply chain.

**Keywords:** Orthopedic instrument; Healthcare reform; Volume-based procurement; Supply chain.

## 1. Introduction

Healthcare reform has been a significant policy focus in China in recent years. The 13th Five-Year Plan for Deepening Medical and Health System Reform of the People's Republic of China proposed to establish a standardized and orderly system for the supply and security of drugs and consumables, which aimed to deepen reform in the field of drug supply, reform the drug distribution system, improve the centralized procurement system for medicines and high-value medical consumables, consolidate and improve the essential drug system, and improve the national drug policy system[1].

Medical devices are one of the three pillars that make up the healthcare delivery system and are an internationally recognized high-tech industry. Government regulation and management of the medical device industry are becoming increasingly stringent. "Regulations on the Supervision and Administration of Medical Devices" has been amended for the third time since it was published in 2000. The new version came into effect on 1 June 2021. In conjunction with the new version of the "Regulations on the Supervision and Administration of Medical Devices", the new version of the "Regulations on the Registration and Filing of Medical Devices" also came into effect on 1 October 2021[2].

Labeling medical devices have become a focus of attention in medical device regulation to visualize the various stages of production, operation, and use and improve product traceability. In 2013, the International Medical Device Regulators Forum (IMDRF) issued guidelines for a unique medical device identification system. In the same year, the United States issued regulations on the unique identification system for medical devices, requiring the full implementation of the unique identification of medical devices in seven years. The European Union, Japan, Argentina, and others have also embarked on related work to promote using the Unique Device Identification[3]. China is

also promoting the use of UDI in an orderly manner. China launched the unified national coding of high-risk medical devices in 2012. In July 2019, the State Drug Administration and the National Health and Health Commission jointly issued the Pilot Work Plan for the Unique Identification System for Medical Devices[4].

In response to national policies, the Internet of Things (IoT), smart healthcare, and third-party logistics-based distribution supply chain model (SPD) have successively become the focus of research by Chinese scholars. As an essential link in the medical supply chain, medical device manufacturers are receiving more and more attention against this background. However, most of the research against the relevant policy background has focused on the hospital end of the supply chain. The need for hospitals to manage medical consumables leanly and provide the best possible patient experience depends on the collaboration of all parts of the healthcare supply chain.

Therefore, to fill a gap in relevant research, this study selects a medium-sized medical device manufacturing company for a field survey, explores its problems in improving the efficiency of the healthcare supply chain, and makes recommendations accordingly.

This paper is organized as follows. Section 2 introduces the case and points out problems. Section 3 analyses the existing issues in the case. Section 4 offers suggestions for the problems.

## 2. Case description

This paper selects an orthopedic consumables company established in 2004 in Soochow, a professional medical device product manufacturer integrating research and development, manufacturing, and sales. This company's vision is to translate the wisdom and experience of Chinese doctors into quality products that truly benefit most patients.

There are seven departments under the general manager's office: the marketing department, finance department, production department, quality management department, technical department, legal department, and available management department.

The company has built a world-class R&D team and has set up a sound product development system with advanced international R&D equipment and a project management system to ensure advanced, effective, and reliable products. Its technical department focuses on the development of products and equipment maintenance. In the five years from 2014 to 2022, it has applied for one trademark, one design patent, three invention patents, and 34 utility patents.

It has also set up experienced production management, a professional marketing team, and an information-sharing logistics and storage system with extension. There are five warehouses, which are severally under the general management department, the production department, and the marketing department. The functions of the available management department encompass human resources management, logistics, and procurement. This department manages three warehouses: the packaging materials store, the raw materials store, and the hardware store. The company employs 116 people, nearly two-thirds working on the production floor where the semi-finished goods warehouse is built. In the semi-finished goods warehouse, semi-finished parts and finished goods without inspection are stored. The marketing department's functions encompass promotion, sales, and customer service. The sales section has two warehouses for finished and returned goods, respectively.

The company has more than a hundred varieties of spinal and trauma implants, with over a thousand specifications. Classified by surgical site, it has 16 types of products. The products are organized according to material and divided into titanium alloy, pure titanium manufactured products, and stainless-steel products. The head of the company's marketing department said that tens of millions of dollars are spent each year on laying out distribution channels.

Against the background of the ongoing reform of China's healthcare system, many problems in the company have come to light. Firstly, the company holds a large amount of inventory over a long period, and inventory management is time-consuming and labor-intensive. Considering that it has thousands of sizes of products, the company keeps tens of thousands of items on hand. Secondly, it has a high rate of book returns and difficulties in counting returned goods. For example, one of the

company's distributors selling to Bortala Mongol Autonomous Prefecture obtained consumables worth RMB 800,000 from the company in early 2022 and returned RMB 500,000 of those goods in August 2022. The distributor's return rate is almost 62% of the goods. In this batch of returns, there were inconsistencies between the packaging and the product, so it wasn't easy to count the returned goods in the warehouse. Such a situation has not been uncommon in recent years. Thirdly, the number of orders received has decreased in recent years. The intensity of the work of the warehouse staff bears this out. With the same quality of staff and technical conditions, it took eight employees a whole day to complete intraday deliveries once upon a time, while now it takes just half a day.

### **3. Analysis of the problems**

#### **3.1 Low level of informatization and intelligence**

This company is a medium-sized enterprise with deficiencies in its information flow and management system. According to previous research, many small and medium-sized enterprises do not have sufficient knowledge about constructing internal control information systems. They tend to position internal control simply as a single management task and focus on production over management, with the finance department taking the lead and supervising all other departments[5]. In its internal management practices, the exchange and processing of information within and between different departments are too simple to improve the efficiency of production operations. The internal information system used by the company is a financial management system. For supply chain management, the company's strategy is more of a record-keeping function for raw materials and finished goods in and out of the warehouse. It cannot meet the demand for supplier management, customer management, and material management.

In its information management, the company relies on human beings to complete it. Only when the employees in the raw material store and production plant find a shortage of raw materials during stocktaking or production will they submit requests for replenishment to the general management department. Then the public management department will send orders to suppliers. This operation can easily lead to production standstills for certain products, thus reducing the response rate to customer orders.

In warehouse management, the use of intelligent storage equipment is missing. Warehouse staff must remember information about thousands of goods, including product type, quantity, and location. In this company, finished products are manually scanned into the computer and sorted into different shelves in different warehouses, piece by piece. When the products leave the warehouse, workers manually pick them up on the corresponding shelves according to the product name on the paper order. In addition, workers must hand-write information, including product specification, place of delivery, recipient, and the number of pieces on the cargo cards glued to the shelves when they receive finished goods from the production plant and paper orders from the sales section. This process takes time and dramatically affects the company's efficiency in fulfilling orders.

#### **3.2 Difficulties caused by specificity and distribution model of orthopedic consumables**

The characteristics of orthopedic consumables result in the company having many stock-keeping units and significant inventory pressure. Orthopedic consumables are characterized by complex specifications, numerous brands, a wide range of surgeries, a strong habit of use by doctors, rapid renewal of consumables, and a high degree of specialization[6]. The different areas of orthopedic surgery and the patient's figure all affect the choice of consumables. An orthopedic operation is a combination of the surgeon, the medical consumables, and the surgical tools, any part of which can affect the outcome. The surgeon in charge will form his habits and preferences for use. Therefore, different doctors will use various consumables for a particular area of orthopedic surgery. In response to the above situation, the company has divided its products into 16 series, according to the surgical site and the patient's age. In addition, orthopedic consumables are available in three materials. The

company's product inventory has 630 types and thousands of specifications of products. As a result, the warehouse has many products to manage.

Due to their characteristics, orthopedic consumables have developed a unique distribution model, creating uncertainty in the returned goods inventory. Because of the particularity of each orthopedic operation, it is impossible to specify the exact type of consumables to be used. Still, often only an approximate range can be established. Consumables are generally stocked on an ad hoc basis according to doctors' orders, and those specific stocking specifications and quantities are mainly reserved by suppliers according to their expertise, following the principle of "more is better than less" to ensure surgical safety. Only during the operation can the specific consumables be identified. Before an orthopedic procedure, all products that fit into this zone are used as a backup. This can lead to a highly complex number and variety of materials in a surgical bag. As shown in Figure 1, the number of orthopedic instruments prepared for an orthopedic procedure is significant. The total number of tools and consumables in the surgical kit ranges from a few dozen to two or three hundred. Many materials in the surgical bag provided by the supplier are non-sterile and must follow a strict sterilization process before they can be used. As a result, many consumables are unpacked in their original packaging. After the surgery, any products that are not used are returned to the supplier. There is also a process of packing back in original packaging and counting involved here, which relies on manual work and is prone to error.



**Fig. 1** Tools that may be used in orthopedic surgery

### 3.3 The impact brought by health care reform policies

The company sees reduced orders from distributors due to implementing policies related to the healthcare industry. These distributors who no longer distribute orthopedic consumables return their remaining stock to the manufacturers, increasing the pressure on the manufacturers' return depots. The reasons for the reduction in orders of distributors are as follows.

Some distributors have chosen to reduce or not sell orthopedic consumables due to plummeting profits because of policy changes. In conjunction with relevant departments, National Healthcare Security Administration has been promoting the reform of centralized volume-based procurement of drugs and high-value medical consumables since 2018. The first six batches of centralized drug and consumables procurement reduced the price by an average of 53%, heart stents by an average of 93%, and artificial hip and knee joints by an average of 82%, which firmly squeezed the profits[7]. In addition, distributors have to bear high labor costs for the additional services. The national policy document on centralized volume-based procurement clearly states that a series of comprehensive services, such as tool allocation, sterilization, and surgical follow-up, are called ancillary services. As suppliers of hospital equipment, commercial distribution enterprises provide supply services, including product delivery and ancillary services[8]. During orthopedic surgery, the manufacturer's distributors, who act as a supplier to the hospital, have to sterilize the medical apparatus and instruments and assist the doctor throughout the operation.

Some of the company's distributors could not participate in the bidding because they did not meet the qualifications. According to relevant policies, the bidding rules, supplier companies' requirements, and product quality are all highly restricted. The listed licensees who have obtained the registration certificate of the drugs within the scope of centralized volume-based procurement can only participate in quantity procurement if they meet the requirements of value-based procurement in terms of quality standards, production capacity, and supply stability. Enterprises participating in value-based procurement should commit to drug quality and supply assurance[9]. Besides, the rules for conducting centralized volume-based purchasing vary from province to province. In terms of the shortlisting criteria for consumables, Jiangsu Province requires products to have procurement records in medical institutions; Fujian Province requires products to have procurement records in public medical institutions at the second level and above and to be listed on the platform typically; Anhui Province sets price shortlisting, stipulating that only companies that accept the shortlisted price are eligible to participate in competitive negotiations; Hunan Province sets technical shortlisting[10]. Thus, the company in the case and its distributors are under pressure to cope with other provinces' different centralized volume-based purchasing requirements.

## **4. Suggestions**

### **4.1 Strengthening links with the downstream supply chain**

The manufacturer, in this case, can reduce the return rate by strengthening its links with downstream distributors and hospitals. This manufacturing company can balance personalization and standardization by collecting surgical data through distributors, analyzing orthopedic consumables in different regions, and customizing generally available configurations in other market areas. In addition, to respond to the individual needs of surgery for orthopedic tools and reduce return and exchange costs, distributors for other hospitals in the same region can be integrated to form a localized supply chain within a particular market area.

### **4.2 Promoting the intellectualization and informatization**

Advanced management information systems and intelligent storage equipment can be used in production and management to reduce labor costs and improve operational efficiency. Within the enterprise, managers should establish a sense of participation in information management and cover the application of the new management system to all departments and positions to integrate information and share resources. This orthopedic consumable manufacturer should optimize the management information system solution, do an excellent job of system design, analyze the actual needs, add functional modules and strengthen the links between the modules to optimize and synergize modules such as budget management and procurement, warehouse management, and contract management. In production management and warehouse management, it should rely on big data and artificial intelligence, using radio frequency identification (RFID), positioning systems, infrared sensors, and other information sensing equipment to connect items to the internet and exchange information to achieve intelligent identification, positioning, tracking, supervision, and management.

### **4.3 They are actively catering to the pharmaceutical reform policy.**

Medical device manufacturers need to make timely adjustments considering that medical system reform policies such as centralized volume purchasing will continue in the long term. Against the backdrop of increasingly stringent supervision of medical devices, manufacturing companies should continue to improve product quality, increase technological investment, and reshape their supply and sales models. Medical device companies are experiencing declining margins and rising market concentration rates. Small and medium-sized consumables companies need to seek cooperation upstream and downstream in the supply chain, upgrade and transform to create a large-scale consumables product line to establish core competitiveness. In addition, manufacturers should also

take the initiative to boost the unique identification data carriers for medical devices to cooperate with hospitals to achieve intelligent management of medical equipment and consumables. Among the three pages of 1D code, 2D code, and radio frequency tag, the RF tag is superior to the first two data carriers regarding information storage and batch reading. By replacing the 1D code with an RF tag, the manufacturer, in this case, can establish a modern logistics system and centralize the management of all channels. This will reduce the overall cost of the medical device supply chain while making it more transparent, visual, and intelligent.

## 5. Conclusion

This study finds that the companies in the case have problems with a high ratio of returns, inefficient inventory management, procurement management, and significantly reduced order volumes under the impact of healthcare reform. The reasons for these problems are as follows: the existing management information system is not fully functional; there is a lack of sufficient understanding of the application of management information systems; the natures of orthopedic consumables and orthopedic surgery lead to chaos in the two-way logistics process; many distribution companies have stopped distributing orthopedic consumables because their profits have been drastically reduced or they do not have the appropriate qualifications under the impact of healthcare reform. To solve these problems above, manufacturing companies related to orthopedic consumables should accelerate their marketing models, transform their orthopedic products, innovate and develop new orthopedic consumables products, promote the modernization of the orthopedic consumables industry, cooperate with hospitals to realize competent healthcare and intelligent medical supply chain. This study helps small and medium-sized enterprises in the healthcare industry to identify problems in corporate management and to achieve continuous improvement against the background of healthcare reform.

There are still limitations in this study. The study of only one orthopedic medical device manufacturer cannot provide solutions for all small and medium-sized medical orthopedic device manufacturers. Different levels of technology, geographic locations, and distribution models all impact a company's operations and supply chain performance. In the future, more small and medium-sized medical device manufacturing companies will be included in the study to explore alternative ways of sustaining and developing the industry through comparative analysis and in-depth investigation.

## References

- [1] State Council of the People's Republic of China. State Council on issuing the "Thirteenth Five-Year Plan" to deepen Notice on the Plan for Deepening the Reform of the Medical and Health System. December 27, 2017. Retrieved on September 17, 2022. Retrieved from: [http://www.gov.cn/zhengce/content/2017-01/09/content\\_5158053.htm](http://www.gov.cn/zhengce/content/2017-01/09/content_5158053.htm)
- [2] Yue Cao, Zhaojun Guo. Analysis of the Acceptance Review Requirements for Medical Device Product Registration and Change Registration Under the New Regulatory System. *Evaluation and Supervision*, 2022, 7: 1-4.
- [3] Haiyan Zheng, Jingwen Guo, Xiao Lian, et al. Medical device unique identifier (UDI) related regulations. *China AUTO-ID*, 2022,86(5): 73-78.
- [4] National Medical Products Administration. Interpretation of the "Rules for the Unique Medical Device Identification System." September 27, 2019. Retrieved on September 17, 2022. Retrieved from: <https://www.nmpa.gov.cn/xxgk/zhcjd/zhcjdy/qx/20190827104001812.html>
- [5] Weixue Chang. A Preliminary Study on the Construction of Internal Control Information System for Small and Medium Enterprises. *China Circulation Economy*, 2022,4: 31-33.
- [6] Yanbo Zuo, Jie Xu. Computer vision-based automatic identification technology solves orthopedic consumables management pain points. *China AUTO-ID*, 2021,93(6): 63-66.

- [7] Shuyun Zhou. Centralized quantity-based procurement becomes normalized and institutionalized. Over 260 billion yuan in savings over the past three years from state organizations' collective procurement. February 12, 2022. Retrieved on September 17, 2022. Retrieved from: [http://www.gov.cn/zhengce/2022-02/12/content\\_5673241.htm](http://www.gov.cn/zhengce/2022-02/12/content_5673241.htm)
- [8] Hongyu Gao. An example is the discussion and practice of building an intelligent supply chain system for commercial distribution enterprises taking orthopaedic medical device products. SUPPLY CHAIN MANAGEMENT, 2022,2: 78-84.
- [9] General Office of the State Council, PRC. Opinions of the General Office of the State Council on promoting the regular and institutionalized implementation of centralized quantity procurement of drugs. January 22, 2021. Retrieved on September 20, 2022. Retrieved from: [http://www.gov.cn/gongbao/content/2021/content\\_5585228.htm](http://www.gov.cn/gongbao/content/2021/content_5585228.htm)
- [10] Chechen Zheng, Yaodong Zhang, Weiyang Sun, et al. Study on the rules of quantity procurement of orthopaedic medical consumables in six provinces in China. CHINA HEALTH INSURANCE, 2021, 7:51-55.