

# Opportunities and Challenges for Small and Micro Medical Device Companies under the Pandemic from the Perspective of New-institutionalism

## -- Taking Company B as an Example

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**Abstract.** Taking Company B as an example, this paper discusses the problems and influencing factors faced by the small and micro medical device management enterprises under the epidemic situation from the perspective of New-institutionalism. The study has found that there is the problem of substitution of enterprise goals. And the main problems existing in the enterprise structure are the cost aggravation caused by the institutional convergence and the legal punishment brought by the separation of structure and operation. The causes of these problems are composed of elements contained in the institutional and technical environment, such as government policies, cultural norms, efficiency, etc. Furthermore, from analysis, the main rules affecting the survival of small and micro enterprises before and after the epidemic have gradually changed from informal system to formal system.

**Keywords:** New-institutionalism; Medical Equipment; Small and Micro Enterprises.

## 1. Introduction

Medical devices are related to people's life and health, but the domestic medical device industry is in a "small and scattered" pattern. After the pandemic, government regulation has been strengthened, and mergers and acquisitions of medical device enterprises (hereinafter referred to as medical device enterprises) have become an inevitable trend, which brings opportunities and challenges for the survival and development of small and micro medical device enterprises. This study explores the problems and influencing factors of small and micro medical device enterprises - Company B under the pandemic from the perspective of New-institutionalism. It is expected to serve as a guide for the actions of small and micro medical device enterprises under the pandemic and provide a boost to the development of the medical-mechanical industry. According to the results of the study, small and micro medical device enterprises have problems such as target substitution and aggravation of system cost in order to violate laws and regulations, which lead to the violation of laws and regulations. And the factors affecting business operations mainly consist of elements contained in the institutional and technological environments, such as government policies, cultural norms, efficiency, etc.

## 2. Review of Domestic and Foreign Literature

### 2.1 Development of Foreign New-institutionalism Theory

New-institutionalism divides the external environment into institutional and technical environments [1]. The influence of the institutional environment on the organization is reflected in the "legitimacy" mechanism, that is, the institutional power of the organization to adopt external opinions. The influence of the technical environment is reflected in the efficiency mechanism, which is the pursuit of organizational efficiency and profit maximization.

The organization is not influenced by the institutional environment or the technological environment only, but by both. The requirements of the institutional environment and the technological environment are often contradictory, and when an organization attaches importance to one, it is likely to neglect the other, leading to problems in management operations and causing

conflicts within the organization. Meyer points out that when faced with conflicts between legitimacy and efficiency, organizations respond by establishing informal constraints to guide their operations instead of formal institutions [2]. However, the separation of formal systems from informal norms does not fundamentally resolve intra-firm conflicts. According to North, the complementarity, adaptability and compatibility between formal institutions and informal constraints should be emphasized, otherwise "there will be a constant tension between informal constraints and formal rules because they are not consistent in many respects" [3].

## 2.2 Domestic Studies on New-institutionalism

Based on organizational sociology neo-institutionalism, domestic scholars have extended the theory of New-institutionalism to the analysis of market structure and operation, and applied the modified theoretical framework to empirical studies. As far as the study of enterprises is concerned, neo-institutionalism focuses on how enterprises create and maintain their "legitimacy" in the market to ensure their survival and development.

Outwardly, enterprises tend to seek cooperation models such as alliances: first, government-enterprise alliances. In his study of the "Sunan model," Zhang pointed out that business operators can use their networks of contacts in politics to expand their business networks and enhance their socio-economic status [4]. It has also been pointed out that the relationship between government and enterprises is the key to the survival of enterprises - government departments at all levels hold a lot of scarce resources for the survival and development of enterprises, which causes enterprises to rely on government resources and also makes them bound by the strong relationship between government and enterprises [5].

Second, alliance with non-governmental organizations. From the point of view of legitimacy acquisition, the alliance with NGOs is beneficial for enterprises to establish a good social image and enhance their own legitimacy [6]. From the perspective of efficiency, maintaining good relationship with community stakeholder network will make the company more competitive and beneficial to increase the performance of the company [7].

Third, participation in business alliances. In their study of Wenzhou's private chamber of commerce, Chen et al. pointed out that when the formal system does not work, the establishment of alliances among enterprises can effectively safeguard the interests of member enterprises and thus promote the healthy development of the industry [8]. At this point, the autonomous governance mechanism formed by the guilds assumes the role of the informal system.

Inwardly, firms will adjust their corporate strategies or governance models based on changes in the institutional environment. Previous studies have analyzed the synergy between the institutional and technological environments: as a result of external institutional pressures, firms' rational behavior patterns change, which is a kind of "constructed rationality" constructed by institutions. In reality, however, this "constructive rationality" is often a "maximization of efficiency" or "science" packaged to "enhance legitimacy, stability, and the power of relevant actors. The "constructive rationality" is often an "irrational behavior" packaged by "efficiency maximization" or "science" to "enhance legitimacy, stability, and power of relevant actors" [9].

In summary, domestic research proves that the structure and behavior of firms are closely related to the institutional environment in which they operate, and that corporate actions and structures appear to be the most rational market behavior, but are in fact the product of social constructs and are strongly influenced by the external institutional environment. Therefore, a sociological analysis of firms is essential. In this paper, Company B is selected for a case study, and in-depth interviews are conducted with Mr. Zhang, the general manager, Ms. Wang, the manager of the finance department, and Ms. Zhang, the manager of the sales department. Professor Wang Ning pointed out that the common characteristics of an individual can better reflect the overall situation is called "typicality", according to which, the common characteristics should be used as the measurement standard for this study if we want to extrapolate to "Chinese small and micro medical device business enterprises". According to the general standard [10], a micro and small enterprise is defined as having less than 5 employees

or operating revenue of less than 10 million RMB. Company B is known to have 4 employees and annual operating income of about 1 million yuan. Currently engaged in Class I and II medical devices, operating well, with stable suppliers and customers. Thus, Company B has certain typicality and the conclusion is generalizable.

### 3. Theoretical Framework

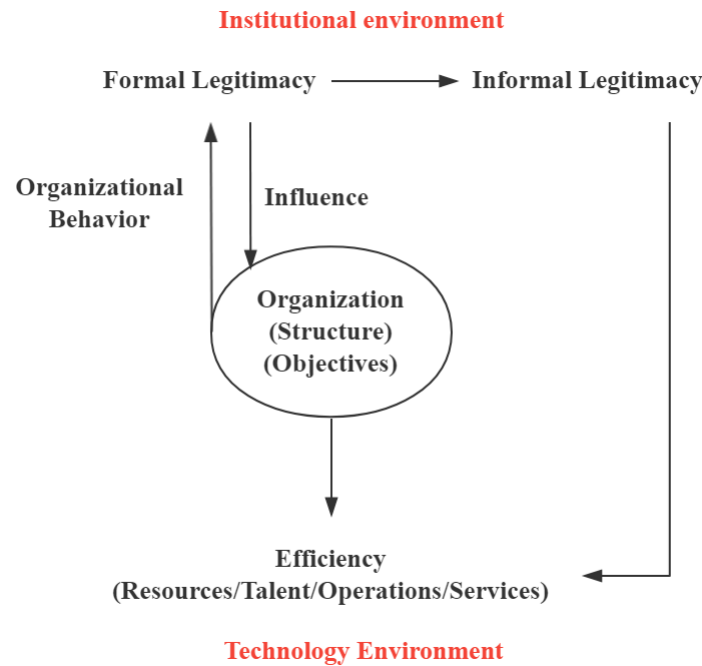


Figure 1. Theoretical Framework

This paper focuses on the influence of institutions on organizations, so the theoretical framework is constructed with legitimacy as its core. Legitimacy includes not only legal institutions, but also cultural expectations, social norms, conceptual institutions, and other social facts that are "widely accepted" by people.

Scott (1995) [11] divides the institutional elements that bring legitimacy into three parts: normative institutions (professional standards, professional standards), regulatory institutions (laws and regulations), and cognitive institutions (customs and social norms). The author drew on Scott's view to classify "legitimacy".

Since the medical device guilds are basically government-affiliated organizations [12], and the regulatory system is compatible with the normative control system, this paper unifies regulatory legitimacy and normative legitimacy into formal legitimacy, which refers to the formal authorization of the organization's actions, and is judged by the existence of formal proclamations of support for the organization's daily work.

This paper further defines customs, culture, and other constraints as informal legitimacy, i.e., the extent to which people express support for organizational structures and actions.

In addition, technical environmental factors are also added to the framework. The New-institutionalism considers an open system between the organization and the environment, when faced with different requirements of the institutional and technological environments, organizations may act differently.

## 4. The Main Problems Faced by Enterprises under the Pandemic

### 4.1 Problems Faced by Business Objectives

1. The negative impact of relationship culture on business operation before the pandemic

Although the relationship strategy helps enterprises to establish good cooperation relationship, it also brings some negative effects. First, the generalization of rights leads to the deviation of corporate goals from the principle of market fairness. Enterprises use interpersonal relationship capital to exclude outsiders from accessing such resources, deviating from the market competition strategy, which has an adverse impact on the market environment and leads to a reduction in overall market efficiency. Mr. Zhang said that it is more difficult for companies to develop new customers - "unless there is a relationship, there is no hope at all", which shows that limited by the relationship network, companies are prone to fall into a comfort zone, and the breadth of choice and information access is limited.

In addition, personal relationships can be costly to business. During the pandemic, companies chose not to raise prices and continue to supply hospitals even when they faced the risk of shrinking profit margins or even losing money in order to "return favors" and maintain relationships with hospitals - "We want to We have to maintain the relationship, so as long as we do not lose too much, we will continue to send" (Ms. Wang). This shows that business operation based on personal relationships brings high costs of interpersonal interaction and leads to inefficient business operation. Human relations have changed from a "resource" to a "liability", and the goal of enterprises has changed from market competition to maintaining "human relations".

#### 2. The existential crisis faced by enterprises after the pandemic

First, the tax burden of enterprises has increased. The third-party group adopted a centralized competitive procurement method to integrate the products of various MSMEs and then unified distribution to medical institutions. In order to deduct input tax, it required MSMEs to provide special VAT tickets, which caused an increased tax burden on MSMEs - "We invariably increased the tax cost by 13%, which is exploitation" (Ms. Wang). According to the Announcement of the State Administration of Taxation on Issues Relating to the Administration of VAT Exemption Policy for Small-Scale Taxpayers, small-scale taxpayers are exempt from VAT if they engage in taxable sales of VAT and their aggregate monthly sales do not exceed 150,000 yuan [13]. The Provisional Regulations of the People's Republic of China on Value-Added Tax also stipulate that no VAT special invoice shall be issued if the tax exemption applies to the occurrence of taxable sales acts [14]. Therefore, not only are MSMEs unable to enjoy tax exemption benefits by issuing special invoices to large distribution enterprises, they will also cause sales to rise above the tax exemption threshold and become the ultimate tax bearers in the VAT flow chain.

Secondly, the sales channels of small and micro enterprises are seized and their legitimacy is reduced. After entering the hospital sales channel, the third-party group's control over MSMEs is also increasing - "for the platform, it has a lot of choices and can completely not choose us, but for us, we only have L as a big customer, there is no choice" (Mr. Zhang) This shows that after the sales channel was seized, the micro and small enterprises gradually lost their right to speak, and their monopoly position, which used to be due to "human relations", no longer exists.

Thirdly, MSMEs are facing fierce competition and difficulties in survival in the market. The Group guides small and micro enterprises to engage in fair bidding - "To get the right to sell products, we have to bid, and whose price is lower, the platform will use to sell to customers" (Mr. Zhang), which, from a macro perspective, is not only beneficial to the healthy development of the industry, but also Eliminate the cost-plus pricing, so that medical equipment competition back to low-price competition, reducing the burden on consumers and society. However, for individual micro and small businesses, increased competition will cause a decline in profits, which will pose a greater challenge to their survival and development in the wake of the pandemic.

## 4.2 The Main Problems Facing the Corporate Structure

### 1. Institutional convergence causes increased costs

New-institutionalism believes that under the compulsion or temptation of institutions, organizations will show institutional convergence, that is, they will show the same structure or behavior to adapt to the same institutional environment. For small and micro medical and mechanical

business enterprises, institutional convergence is specifically reflected in the establishment of quality management departments. First of all, Mr. Zhang thinks that system convergence will cause an increase in labor costs - "we small enterprises, hire a professional, have to pay wages, but also have to give welfare benefits, the calculation is to lose money. In addition, the practice of business management system requires a large investment of time costs. Ms. Wang believes that the management of the warehouse will reduce the efficiency of the daily operations of the business - "warehouse temperature measurement is very time-consuming. Ms. Zhang, on the other hand, believes that "hospitals need goods urgently during the pandemic, and the warehouse inspection takes time", so it is clear that following the system process will affect the efficiency of delivery and transportation, which may have a negative impact on the survival of the partnership between the company and the hospital.

In summary, the phenomenon of organizational convergence has caused an increase in the operating costs of MSMEs. Due to the lack of size and capital of MSMEs, the restructuring of the enterprise to fit the institutional requirements makes them bear heavier institutional costs and leads to a decrease in operational efficiency. Therefore, the establishment of quality department not only fails to bring profit, but also requires a large amount of capital to maintain the operation, and the institutional cost outweighs the benefit, imposing a burden on the enterprise.

## 2. The separation of structure and operation brings legal penalties

Because the institutional costs outweigh the benefits gained, organizations often choose to separate the formal structure of the organization from the actual operation. While this improves corporate efficiency, it can also lead to a loss of legitimacy. Data show that in 2020, regulatory agencies at all levels found that there are violations of the medical device business enterprises up to 3.51 times [15], it is clear that there are more serious irregularities in the operation of medical devices. B enterprises also have a separation of structure and operation, which is manifested as one person with multiple posts.

Multiple positions for one person led to violations of laws and regulations in the enterprise. Mr. Zhang reflected that in order to save labor costs, he was the general manager and also the manager of the quality management department and the comprehensive department (see Figure 2 for the internal structure of the enterprise), but due to the inability to cope with the situation, there were loopholes in the operation of the enterprise and was punished by law - "during the flight inspection, it was found that the company's incoming goods inspection The records were faulty and incomplete, and were required to rectify the situation within a certain period of time". As can be seen, with the increased government monitoring after the pandemic, the relationship between the informal operating rules and the formal system of micro and small enterprises has become tenser, making it difficult to muddle through irregular business practices and vulnerable to government penalties, leading to problems such as reduced legitimacy and damaged reputation.

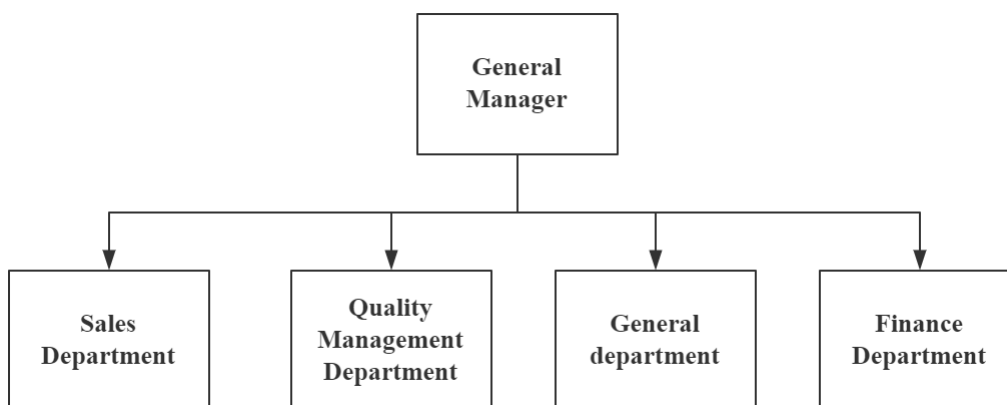


Figure 2. Internal Structure of Enterprise B

## 5. Main Factors Affecting Enterprises

### 5.1 Main Factors Affecting the Objectives of the Enterprise

#### 1. The main role of relationship culture before the pandemic

The New-institutionalism believes that institutions do not only refer to governmental acts, but also include "widely" accepted cultural and social norms. Unlike the West, which emphasizes formal rules, in China, organizational action emphasizes more informal rules, leaving more room for private relationships to operate. Fei Xiaotong has suggested that the grassroots structure of Chinese vernacular society is a "differential pattern," a "network of private ties," which is different from the modern Western "group pattern. Each knot of this network has a moral element attached to it, and all the value standards cannot exist beyond the differential order of human ethics. Thus, it can be seen that relational culture, as the social relationship norms of Chinese people, has the value identity and behavioral tendency of legitimacy.

Previous research has confirmed that in a market environment lacking effective legal regulation, firms gain legitimacy primarily through compliance with relationship strategies [16]. Before the pandemic, when legal regulation was weak, Ms. Zhang, who is the head of the procurement department at Hospital L, played a huge role in the establishment and maintenance of the partnership between the hospital and Company B - "I facilitated the search for Hospital L to cooperate, there was no need for bidding and evaluation, and there was this trust between acquaintances themselves" (Ms. Zhang). It follows that when formal institutions do not work, it is easier for firms to gain external stakeholder support and reduce the risk of entering the market by following the prevailing relationship strategy. However, this also leads to a shift in corporate objectives away from market competition and towards "maintaining human relationships", which leads to a reduction in the overall efficiency of market operations.

#### 2. The strong involvement of third-party logistics platforms after the pandemic

Institutional changes have also influenced corporate goals and actions. Selznick, a neo-institutionalist scholar, points out that powerful interest groups can change policy goals, and welfare to the disadvantaged is turned into an instrument of power. As can be seen, organizational goals change as the institutional environment changes, and firms must passively incorporate some of their official goals into their own goal system to gain more official legitimacy in order to obtain the resources necessary for survival, even if this makes them less efficient.

Medical device third-party logistics platform won policy support after the pandemic [17] [18]. Data show that in 2020, the number of medical device third-party logistics enterprises reached 574, with an increase of 15.96% [19], which also caused difficulties in the survival of small and micro enterprises. On the one hand, the legitimacy of enterprises established and maintained through "favors" has been abolished. On the other hand, the legitimacy of the company was obtained in exchange for lower profits, which also caused the loss of efficiency.

Thus, the objectives of company B are influenced by the system. If we consider the organizational stakeholders and their evaluation criteria as a magnetic field that exerts influence on them as an "organizational field". Then the manufacturer, company B, hospital L, and company G all exist in an organizational field of medical devices. It is not only the beneficiary of the system (mainly government policies), but also the developer of the system (business practices, norms) and the provider of legitimacy resources, which plays a decisive role in the organizational goals. The original primary goal of the enterprise is to sell medical devices to hospitals and thus make profits and maintain the survival of the enterprise. However, in the actual operation of the enterprise, due to the influence of enterprise G, company B had to change its cooperation method, which led to the increase of tax burden, the increase of operation cost and the reduction of profit margin. However, due to the requirements of institutional standardization, the strong position of the third-party logistics platform (large enterprises) and the need to maintain their survival, the enterprises have to accept the institutional environment and adjust the partnership between profitability and maintenance of the hospital to obtaining sufficient official recognition to maintain the existing resources and participate

in fair competition in the market. Thus, the involvement of powerful interest groups controls the setting and operation of the system, thus causing a deviation from organizational goals.

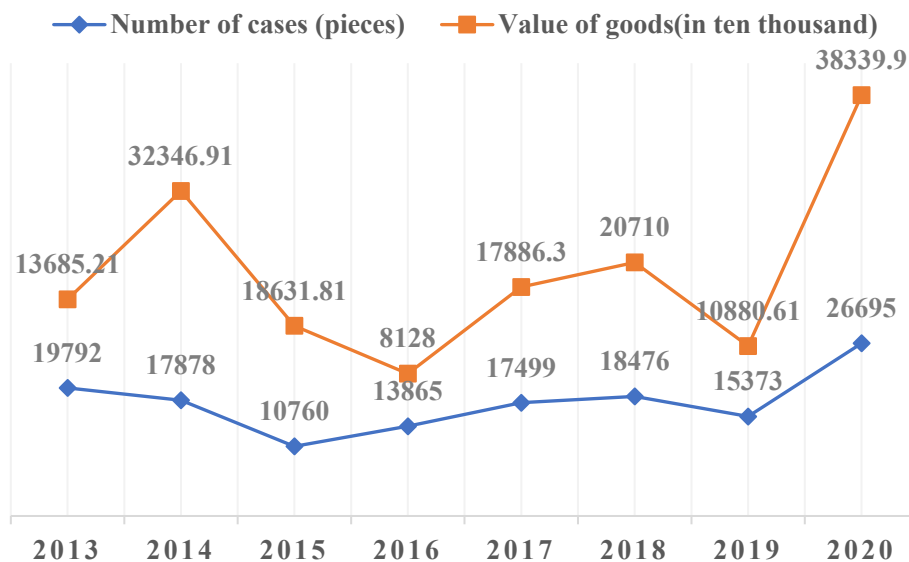
### 5.2 Main Factors Affecting the Structure of Enterprises

#### 1. Impact of government policy formulation and implementation

The pandemic the impact of government policy formulation and implementation on firms has changed before and after the pandemic. According to the New-institutionalism, under the coercion or temptation of institutions, organizations will show institutional convergence, i.e., organizations will show the same structure or behavior in order to adapt to the same institutional environment. Before the pandemic, the impact of policy on MSMEs was manifested as organizational structural convergence. According to the law [20], "setting up a quality management department" is the threshold for entry into the business. company B set up a quality management department to gain legitimacy for its operations, but due to the lack of daily monitoring, the formal structure was not implemented, but "suspended" in the organizational itinerary as "idle."

After the pandemic, policy settings and administrative efforts were simultaneously improved, and the influence of the system and the organization shifted from structural convergence to actual operational convergence. From the policy set-up, supervision, the state added a new team of full-time inspectors to strengthen the daily supervision and inspection of medical devices. In terms of punishment, the revision of the *Regulations on Supervision and Administration of Medical Devices* [21] has increased the penalties and clarified the rights and responsibilities of each subject (corporate bodies and relevant government departments).

In terms of administrative enforcement, small and micro enterprises face more stringent inspections. Data point out that in 2020, after the revision of the Regulations, 26,695 medical device cases were investigated and handled, with an increase of 42.32% year-on-year, and the monetary amount of 383,399,000 yuan, with an increase of 251.38% year-on-year (Figure 3).



**Figure 3.** Comparison of The Number Of Medical Device Cases, I.E., Monetary Amounts, 2013-2020 [22]

The institutional change forced Company B to adjust its organizational operation model to accommodate the stricter institutional controls. However, constrained by capital and size, the informal operation of enterprises has difficulty keeping up with the new formal system requirements - "it is really difficult for us to meet the stricter standards in our current operation" (Ms. Wang). The legitimacy and market competitiveness of MSMEs are weakened, and their survival is threatened.

#### 2. Impact of market normative requirements

Enterprises use the symbolic meaning of formal structure to "package" themselves and enhance their legitimacy - "We are not as high-end as other large enterprises, so we use materials to package ourselves so that people will be more willing to trust us. We, business is also good to talk." (Mr. Zhang) It can be seen that compared to large enterprises operating international high precision and big brand products, small and micro business enterprises operating low- and medium-end products consumable products do not occupy an advantage, and it is difficult to obtain legitimacy through technological monopoly, so their structure and actions are more susceptible to the influence of the system, i.e., to establish a structure in line with institutional norms to cope with normative requirements and not to be expelled by the market.

### 3. Influence of technological environment

The technological environment requires firms to pursue operational efficiency and control operating costs. The New-institutionalism suggests that the systems and structures set up to meet government requirements may be separated from the actual operation of the organization. As we can see from the "vacancy" of the quality department of Company B, when the institutional cost of operating the organizational structure is greater than the benefit, the formal structure will be separated from the actual operation, and the function of controlling the daily work within the enterprise will be lost.

It can be seen that corporate strategy is the result of the synergy between institutional and technical environments, and that organizations do not accept institutional requirements as they are, but make conscious choices and play games driven by interests, forming a kind of "rational behavior under the establishment".

## 6. Conclusion and Implications

### 6.1 Conclusion

The study found that the main rules affecting the survival of micro and small medical and mechanical enterprises changed before and after the pandemic. Analysis from the New-institutionalism perspective shows that this is caused by the change in the intensity of control of the technical and institutional environment on the micro and small enterprises before and after the pandemic. Before the pandemic, as the formal system was not well developed, meeting the requirements of the technical environment was the primary goal for micro and small medical device enterprises. Therefore, from the perspective of enhancing operational efficiency, enterprises obtained market access through the informal system to gain legitimacy for the benefit of the enterprise. In the post-pandemic period, with the change of the regulatory system of medical device operation, the formal system becomes stronger in controlling the enterprises. Relationship strategies have relatively weaker control over firms, and the space for private relationships to operate is shrinking. At the same time, the benefits of informal systems decrease and the benefits of formal, rules-based arm's-length transactions enforced by third parties are increasing. In order to survive, the primary goal of micro and small medical and mechanical enterprises has gradually shifted from meeting the requirements of the technical environment to meeting both the requirements of the institutional environment and the technical environment, or even to meeting the requirements of the institutional environment. Accordingly, the enterprise strategy becomes market-centered, and the enterprise structure gradually changes from the previous formal convergence to the actual structure and action convergence. Formal legitimacy has a greater role in improving the chances of survival and competitiveness of the firm than informal legitimacy.

It can be seen that the emergence of the pandemic stimulated the national demand for normality in the medical device industry, which in turn drove the change in the system related to the operation of medical devices. In response to the pandemic prevention and control requirements, the accumulated momentum of formal institutions began to overcome the inertia of traditional relational culture in the deep structure, and the industry entered a new phase based on a formal rule, i.e., a shift from cooperation based on relational order to cooperation with a formal third-party logistics platform,

which certainly required a long quantitative process, although it compressed the circulation links and promoted fair transactions in the market. The New-institutionalism points out that MSMEs are influenced by both formal and informal systems, and the interaction between formal and informal systems is also very complex. On the one hand, the formal system is still inadequate and will take a long time to improve - the survival problems of MSMEs due to high taxes and fierce market competition have not yet been solved. On the other hand, the influence of the informal system, such as the relationship culture, is inertial, and companies may still "exploit legal loopholes" and potentially collude with hospitals or other partners to hinder the implementation of the formal system.

## 6.2 Insights

After the pandemic, the system has put forward higher requirements for the operation of micro and small medical device enterprises, but at the same time, it has also brought certain challenges to the survival and development of micro and small enterprises. Therefore, after the pandemic, we should continue to improve the relevant systems in medical device operation and find a balance between the survival of micro and small enterprises and standardized operation. From the perspective of the New-institutionalism, the author combines the impact of formal and informal systems on the organization, and discusses it in both internal and external aspects of the organization, making the following recommendations.

From the external perspective of enterprises, the government should promote the merger and reorganization of large enterprises to small and micro medical equipment business enterprises. The large medical equipment business distribution enterprises can obtain the network channel resources of hospitals by merging and reorganizing small and micro enterprises. At the same time, the merger of small and medium-sized enterprises can enable large enterprises to expand their distribution channels to the terminal hospitals in each region, reduce the distribution links of medical devices and lower the distribution costs, which on the one hand is conducive to the reduction of medical product prices and the maintenance of market order. On the other hand, replacing unified procurement with mergers and reorganization can reduce the pressure of tax payment and competition for small and micro enterprises, and avoid squeezing the benefit space of small and micro enterprises. However, because the products made by micro and small enterprises are relatively single and their profit margins are low, large enterprises are currently not willing to make acquisitions of them. Therefore, in the future, we should make further adjustments in the formal system to support small and micro enterprises, and guide large medical device enterprises to degree small and micro enterprises for mergers and acquisitions to expand their living space.

From the internal point of view of the enterprise, the formal system should be set up to fit the existing development situation and actual needs of small and micro enterprises. For example, the operation of the quality department may bring a heavier institutional burden for micro and small enterprises, therefore, the government can encourage multiple micro and small enterprises to share a quality management department or institution to save resources, so that the formal system does not only remain in the symbolic sense, but to play a practical help and management role in the standardized development of micro and small enterprises. In this way, micro and small organizations can be widely recognized and supported by governments, financial institutions, and society at all levels in terms of jurisprudence, recognition, regulation, and control, and reduce and get rid of the "informal" symbolism.

In addition, at present, enterprises change themselves to adapt to their environment, but lack the ability and path to change their environment. Therefore, we should promote the development of guilds to give micro and small enterprises a platform to express their views and attitudes and defend their interests, and help guide them to adopt appropriate and feasible paths to obtain the legitimacy of their goals.

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