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Financing Difficulties and Coping Strategies of Medical Device SMEs under the Background of New Healthcare Reform

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Abstract: ***This study examines the financing challenges faced by small and medium-sized enterprises (SMEs) in China's medical device industry under the ongoing healthcare reform. It aims to analyze how policy changes such as centralized procurement and DRG or DIP payment systems influence enterprise financing conditions. Using policy analysis and industry-based qualitative assessment, the study identifies key constraints including reduced internal financing capacity, limited external financing channels, and structural mismatches between financing supply and demand. The findings indicate that policy-induced profit compression and increased compliance costs significantly weaken financial resilience, while traditional financial systems inadequately support asset-light and innovation-driven firms. The study proposes multi-level strategies involving enterprises, financial institutions, and government to improve financing accessibility and efficiency. These findings contribute to policy optimization and support the sustainable development of the medical device industry.***

Keywords: Healthcare Reform; Medical Devices; Small and Medium-sized Enterprises; Financing Dilemmas; Healthcare Policy; SME Financing; China Medical Industry

1. Introduction

Since the launch of the new medical reform in 2009, systematic reforms have been continuously advanced based on the principle of "ensuring basic coverage, strengthening grassroots level, and establishing mechanisms", and further deepened in the "14th Five-Year Plan" period. The centralized procurement has expanded from chemical drugs to all types of medical devices, DRG/DIP payment has been fully implemented, the registration system for medical device manufacturers has been further promoted, the tiered diagnosis and treatment and new medical infrastructure construction have been accelerated, profoundly changing the industry ecosystem. It has brought opportunities such as import substitution and expansion of the grassroots market for domestic enterprises, but also raised higher requirements for innovation capabilities and compliance operations.

As a strategic emerging industry, more than 90% of the production enterprises in the medical device sector are small and medium-sized enterprises, which are the core force in the chain integration and technological innovation. However, they generally have small scale, light assets, long research and development cycles, and high risks. In the new medical reform framework, their anti-risk ability and profit stability have become prominent shortcomings, and problems such as difficulty in financing, high cost of financing, and slow financing process have been prominent. Although existing studies have formed a relatively mature theoretical framework, they mostly focus on pharmaceutical production or small and medium-sized enterprises in the entire industry, lacking systematic and in-depth analysis of the latest policies' impact on centralized procurement normalization, DRG/DIP reform, etc. under the context of the deepening of the new medical reform.

Accordingly, this paper, based on the latest policy environment, combines the characteristics of the medical device industry and the development characteristics of small and medium-sized enterprises, systematically analyzes the financing difficulties and their underlying causes, and proposes multi-dimensional coping strategies, with the aim of providing practical references for solving financing problems and promoting the high-quality development of the industry.[1]

This study adopts a qualitative analytical approach centered on policy review and industry characteristic analysis, with a clear and reproducible research framework. First, we systematically sorted out core policy documents of China's healthcare reform from 2009 to the present, including the normalization rules of volume-based centralized procurement, the full implementation plan of DRG/DIP payment methods, the Medical Device Registrant System (MAH) and other key regulatory policies, with clear selection criteria of policies that directly affect the operation and financing environment of medical device SMEs. Second, we integrated industry operation data, financing status statistics and typical enterprise operation characteristics released by the National Medical Products Administration, China Medical Device Industry Association and other authoritative institutions, to assess the dual impact of healthcare reform on the financing environment of SMEs. Third, we conducted a three-dimensional analysis of the underlying causes of financing difficulties from the perspectives of enterprises, financial system and policy environment, and proposed targeted collaborative strategies. The entire research process is based on public authoritative policy documents and industry data, ensuring the rigor and traceability of the research conclusions.

2. The Dual Impact of the New Medical Reform on the Financing Environment of Medical Device Small and Medium-sized Enterprises

2.1 Policy Opportunities for Financing of Medical Device Small and Medium-sized Enterprises brought by the New Medical Reform

The continuous deepening of the new medical reform has created a broad market space and policy dividends for medical device small and medium-sized enterprises, providing a favorable fundamental support for their financing. The continuous implementation of domestic substitution policies has promoted the domesticization of high-end medical devices, encouraging small and medium-sized enterprises to focus on specialized tracks and take the "specialized, innovative, and distinctive" development path.[2] Small and medium-sized enterprises with core technologies have entered a development window in fields with high dependence on imports. The technical value and market space have been widely recognized by the capital market.

The comprehensive promotion of the registration system for medical device manufacturers (MAH) allows for the separation of research and production, significantly reducing the fixed asset investment and initial research and development costs of small and medium-sized enterprises, shifting the core value from fixed assets to patents, registration certificates, and other intangible assets, creating conditions for the financing of intangible assets.[3]

The improvement of the tiered diagnosis and treatment system and the promotion of new medical infrastructure construction have continuously released the demand for upgrading medical equipment at the grassroots level, providing stable market growth for small and medium-sized enterprises with cost advantages and service capabilities, and enhancing their credit qualifications in financial institutions. In addition, the special credit support, financing guarantees, and interest subsidies for specialized and innovative small and medium-sized enterprises have been continuously implemented by the state, and many banks have set up exclusive credit products, effectively reducing the financing threshold and cost for specialized and innovative small and medium-sized enterprises in the medical device sector.[4]

2.2 Challenges and Pressures on Financing of Medical Device Small and Medium-sized Enterprises brought by the New Medical Reform

The new medical reform has profoundly restructured the industry's profit model and competition pattern through policies such as the normalization of centralized procurement and DRG/DIP payment reform, significantly impacting the financing of small and medium-sized enterprises. The normalization of centralized procurement has led to an average price reduction of over 50% for the winning products in some categories, with a reduction of over 90%. Small and medium-sized enterprises without core technologies, regardless of whether they win the bid or not, have their profit stability severely impacted. The risk appetite of financial institutions and investment institutions has significantly decreased, and the financing supply has continued to shrink.

The DRG/DIP payment reform has changed the hospital's procurement behavior, with hospitals more inclined to choose cost-effective products and significantly extending the payment cycle. In some regions, the payment cycle has extended to over 12 months. Enterprises face both revenue decline and cash flow pressure, and their internal financing capacity and credit qualifications have been weakened.

The implementation of the two-ticket system, UDI system, GMP and other regulations has significantly increased the compliance costs for small and medium-sized enterprises in production, circulation, and taxation.[5] Some enterprises are at risk of suspension and rectification, and the increase in compliance risks further raises concerns among financial institutions regarding credit granting. At the same time, the new medical reform has promoted the continuous improvement of industry concentration, with leading enterprises expanding their market share by leveraging their scale, technology, and channel advantages. Small and medium-sized enterprises, on the other hand, are at a disadvantage in terms of cost control, technological research and development, and marketing, resulting in a continuous shrinkage of market share and an increase in operational risks.[6] Financial institutions and investment institutions tend to channel their funds towards leading enterprises, further exacerbating the financing difficulties of small and medium-sized enterprises.[7]

3. Core manifestations of financing difficulties for medical device small and medium-sized enterprises under the new medical reform context

3.1 Continuous weakening of internal financing capacity and continuous expansion of cash flow gap

The new medical reform has fundamentally weakened the internal financing capacity of medical device small and medium-sized enterprises. The implementation of centralized procurement and DRG/DIP reforms has led to a significant decline in industry gross profit margins. The gross profit margins of products winning centralized procurement tend to drop to below 20%, and the retained earnings of enterprises have shrunk significantly. At the same time, the strong position of public hospitals has prolonged the collection cycle of accounts receivable to over 6 months, and in some regions, even over 18 months. The continuous increase in compliance, research and development, and marketing costs has squeezed both the revenue and expenditure sides, causing continuous pressure on operating cash flow.

In addition, medical device R&D is costly, long in cycle, and high in risk. The average time from R&D to obtaining certification for three types of products is 3-5 years, but the centralized procurement policy makes the expected profit after listing highly uncertain, reducing the willingness of enterprises to invest in internal financing. This has formed a vicious cycle of insufficient R&D, weakened competitiveness, and declining profitability, with the continuous weakening of internal financing capacity becoming the core root cause of the financing difficulty.

3.2 Structural imbalance in external financing channels and severe mismatch between financing supply and demand

Under the weakened internal financing capacity, the construction of external financing systems lags behind, resulting in a severe mismatch between financing supply and demand. In indirect financing, bank credit still relies on fixed asset mortgage as the core, while medical device small and medium-sized enterprises mostly operate with light assets, with core assets being intangible assets such as patents and registration certificates.[8] The collateral financing system is not well-developed, making it difficult for enterprises to obtain sufficient credit support. Even if they obtain credit approval, they face issues such as low credit lines, long approval processes, and high guarantee requirements. In direct financing, the listing thresholds for the Main Board, ChiNext Board and STAR Market are high, and the Beijing Stock Exchange also has clear profit and market value requirements, making it difficult for most enterprises to meet the standards. The liquidity and financing functions of the new third board and regional equity markets are poor, bond issuance has high thresholds, and small and medium-sized enterprises are unable to participate.[9] Other financing channels, such as venture capital institutions, due to the uncertainty of centralized procurement policies, tend to be conservative in investment and postpone the early stage, increasing the difficulty of early-stage project financing, supply chain finance has limited effectiveness due to the difficulty of transmitting the credit of core enterprise, and financing channels such as leasing and commercial factoring have low adaptability and cannot form effective supplements.

3.3 High financing costs and severe mismatch between financing terms and enterprise operating cycle

Medical device small and medium-sized enterprises also face high financing costs and a severe mismatch between financing terms and operating cycles. In terms of financing costs, the loan interest rates for small and medium-sized enterprises are generally between 6% and 8%, which is more than 30% higher than those of leading enterprises. Some channels even exceed 15%. Coupled with hidden costs such as guarantee fees and assessment fees， the high financing costs further erode profits, causing enterprises to fall into a vicious cycle of "financing - loss - re-financing". In terms of financing terms, the time from R&D to listing for three types of medical devices is 3-5 years, and after listing， there is a 2-3-year market promotion period. The financing demand cycle is long, but financial institutions provide mainly short-term working capital loans with a term of less than one year, and there is a scarcity of medium-term credit support. Enterprises are forced to "short-term use long-term funds" and face continuous refinancing pressure and risks of financial chain rupture. Furthermore, under the new healthcare reform, policy uncertainty has further increased the financing risk premium. Financial institutions have covered the risks by raising interest rates or lowering valuations, making the financing conditions for small and medium-sized enterprises even more stringent.

4. Deep-seated Causes of Financing Difficulties for SMEs in the Medical Device Industry under the New Medical Reform

4.1 Insufficient Core Competitiveness and Lack of Governance Norms

The insufficient professional service capabilities of the financial system for the medical device industry is the core external factor of financing difficulties. The banking system still bases credit granting on fixed asset mortgage and profit levels, lacking a professional risk assessment system tailored for the characteristics of medical device light assets, long cycles, and high risks. Their ability to identify the value of intangible assets is weak, making it difficult for innovative SMEs to obtain credit support. The supply of specialized financial products is insufficient, with products such as intellectual property pledge, registration certificate pledge, and medium-term R&D loans having high implementation barriers and poor adaptability.

In the capital market, the listing threshold still focuses on profit indicators, and the financing functions of the new third board and regional equity markets are limited. Early-stage enterprises have difficulty accessing equity financing channels, and venture capital institutions face difficulties in exit and investment willingness. The risk-sharing system is lagging, with insufficient support from policy guarantee institutions, and the lack of effective risk compensation mechanisms for intangible asset pledge financing. Moreover, financial institutions lack professionals in medical devices, further constraining the supply of financing services.

4.2 Insufficient Industry Adaptability and Lagging Risk Management Models

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4.3 Incomplete Supporting Systems and Inefficient Policy Transmission

The incomplete supporting systems and inefficient policy transmission are important institutional factors for financing difficulties. The policy environment supporting the medical device industry lacks specialized design for its characteristics. Core assets such as medical device registration certificates lack clear policy support and supporting systems in pledge financing. The intangible asset pledge financing supporting system is not complete, with inconsistent value assessment standards, scattered and complex registration and registration procedures, and poor channels for disposal and realization, resulting in low acceptance by financial institutions. The synergy between new medical reform policies and financing support policies is insufficient. Policies such as centralized procurement and DRG/DIP have profoundly changed the industry's profit model, but have not simultaneously established financing support mechanisms for SMEs. The policy benefits of the MAH system have not been fully released. Finally, the policy transmission mechanism is inefficient, lacking a one-stop financing service platform. Small and medium-sized enterprises lack understanding and knowledge of policies, and are unable to utilize them effectively, leading to information asymmetry and the inability of many supportive policies to truly take effect.

5. Countermeasures to Solve Financing Difficulties for SMEs in the Medical Device Industry under the New Medical Reform

5.1 At the Enterprise Level

To solve the financing difficulties of SMEs in the medical device industry, the core lies in the enterprises themselves actively adapting to the policy orientation of the new medical reform, focusing on core fields to enhance core competitiveness, standardizing corporate governance to strengthen internal financing capabilities, and fundamentally improving their financing qualifications and credit levels.

Firstly, enterprises should base themselves on the policy orientation of the new medical reform, formulate clear development strategies, focus on specific market segments and take the path of specialized, innovative and distinctive development. Enterprises should deeply analyze the impacts of policies such as centralized procurement and DRG/DIP, avoid the mid-to-low-end market segments that are covered by centralized procurement and suffer from severe homogenization competition, and focus on the development of market segments with large import substitution potential, high technical barriers and small impacts from centralized procurement. Such market segments include high-end implantable medical devices, minimally invasive surgical instruments, household medical devices, POCT rapid diagnostic reagents, rehabilitation medical devices, etc. Enterprises should concentrate resources on core technology research and development, build an independent intellectual property rights system, create differentiated product competitiveness, break free from the predicament of low-price competition, stabilize the profit expectations and development prospects of the enterprise, and fundamentally enhance the credit qualification of the enterprise in financial institutions and the capital market.

Secondly, enterprises should strengthen research and development innovation management, improve the efficiency and success rate of R&D investment. The R&D in the medical device industry has the characteristics of high investment and high risk. Enterprises should establish a complete R&D management system, carry out R&D projects based on clinical needs and policy orientation, avoid blindly following the layout of popular market segments, and at the same time, make full use of the policy benefits of the MAH system, through commissioning production, cooperative R&D and other models to reduce R&D investment and fixed asset costs, shorten the product development and registration cycle, and improve the return rate of R&D investment. At the same time, enterprises should strengthen the management and operation of intangible assets such as patents and registration certificates, establish a complete intellectual property rights management system, conduct comprehensive patent layout for core technologies, and actively connect with professional assessment institutions to evaluate the value of intangible assets, laying the foundation for subsequent intangible asset pledge financing and equity financing.

Thirdly, enterprises should standardize the corporate governance structure, strengthen financial management and compliance operation capabilities. Enterprises should break the limitations of family management, establish a complete modern enterprise system, improve the corporate governance structure, enhance the standardization and transparency of management and operation, and establish a standardized financial management system to ensure the authenticity and completeness of financial statements, improve the financial transparency of the enterprise, solve the problem of information asymmetry with financial institutions. In addition, enterprises should strictly abide by the industry compliance requirements under the background of new medical reform, fully implement GMP norms, two-ticket system, UDI system and other requirements, strengthen compliance management in production, circulation and taxation links, reduce compliance risks, and enhance the credit trust of financial institutions.

Fourthly, enterprises should strengthen cash flow management, improve the ability of internal financing. In the context of continuous weakening of internal financing, enterprises should establish a refined cash flow management system, strengthen accounts receivable management, formulate special management strategies for the collection from hospitals, optimize the credit term agreement with downstream customers, improve the turnover efficiency of accounts receivable, and promote lean production, optimize the cost control system, reduce production and operation costs, improve the profit level and retained earnings of the enterprise, strengthen the core foundation of internal financing. In addition, enterprises should formulate scientific financing plans, establish a professional financing team, deeply understand various financing channels and support policies, according to the financing needs of different development stages of the enterprise, select suitable financing products and channels, build a diversified financing system, reduce financing costs, and avoid financing risks.

5.2 At the Financial Institution Level

Financial institutions should proactively adapt to the financing demand characteristics of small and medium-sized medical device enterprises under the new medical reform context, break away from the traditional credit model, innovate financial products and service models, improve the risk assessment and control system, and build a specialized financing service system suitable for the characteristics of the medical device industry. First, banking institutions should break away from the reliance on fixed asset mortgage, establish a specialized risk assessment system for the medical device industry, and the bank should form a credit approval and risk control team with professional background in the medical device industry, deeply study the development laws, policy orientations and risk characteristics of the medical device industry, establish a risk assessment model centered on technical value, clinical value, and market prospects, incorporate the enterprise's patented technology, medical device registration certificates, R&D capabilities, core team, centralized procurement winning orders, hospital purchase orders, etc. into the credit assessment indicators, no longer take fixed asset mortgage and profit level as the sole standard for credit granting, for specialized and innovative small and medium-sized enterprises with core technologies and good development prospects, lower the credit threshold, simplify the approval process, and increase the credit amount. Secondly, banking institutions should innovate specialized financial products adapted to the characteristics of the medical device industry, based on the R&D cycle and business characteristics of medical device enterprises, launch differentiated credit products, for enterprises in the R&D stage, launch intellectual property pledge loans and R&D special loans based on core patents, provide medium-term R&D funding support; for enterprises that have obtained registration certificates, launch medical device registration certificate pledge loans, provide credit based on the market value of the registration certificate; for enterprises that have won centralized procurement, launch winning order loans, provide working capital loans based on winning orders; for downstream enterprises that are hospitals, launch accounts receivable factoring, hospital order financing, etc. supply chain financial products to solve the cash flow pressure caused by long repayment cycles, and at the same time, for small and medium-sized medical device enterprises, launch medium-term credit products to match the R&D and business cycles of enterprises, solve the problem of "short-term loans for long-term use" of enterprises, and reduce the risk of capital turnover. Thirdly, the multi-level capital market should improve differentiated listing standards, strengthen the financing service function for small and medium-sized medical device enterprises, the Science and Technology Innovation Board and the Beijing Stock Exchange should further optimize the listing standards for innovative medical device enterprises, lower the profit indicators requirements, strengthen the attention to the enterprise's R&D capabilities, core technologies, clinical value, etc., open up the listing channels for high-quality innovative medical device enterprises that have not yet achieved profitability; the National Equities Exchange and Quotations should further improve the tiered system, enhance the financing function and liquidity of listed companies, provide a standardized equity financing platform for small and medium-sized medical device enterprises; regional equity markets should establish a medical device industry incubation zone, provide one-stop services such as equity listing, financing connection, compliance guidance, policy connection, etc. for small and medium-sized enterprises, improve the transfer mechanism between the National Equities Exchange and Quotations and the Beijing Stock Exchange, and build a full-cycle capital market service system. Fourth, venture capital institutions and industrial capital need to establish a comprehensive investment layout covering the entire cycle, increase investment in early-stage medical device small and medium-sized enterprises, and form professional investment teams for medical devices. They should enhance their ability to assess the technical and clinical value of early-stage projects, collaborate with government-guided funds and leading industrial enterprises, establish an early-stage medical device investment fund, improve the risk-sharing mechanism, increase investment in seed-stage and start-up-stage medical device small and medium-sized enterprises, and provide value-added services such as industry resource connection, compliance guidance, and R&D management to investment enterprises to accompany their growth. Additionally, they should encourage leading enterprises in the medical device industry to establish industrial investment funds, carry out investments along the upstream and downstream of the industry chain, provide industry resources and financial support to small and medium-sized enterprises, and promote the coordinated development of the industry chain. At the same time, they should improve the exit channels for venture capital institutions to provide effective exit paths for early-stage investments and further stimulate the investment willingness of venture capital institutions.

5.3 Government Level

The government should base itself on the policy framework of the new medical reform, improve the supporting policy system for financing of medical device small and medium-sized enterprises, break through the "last mile" of policy implementation, and establish a multi-party collaborative financing support and risk-sharing mechanism to provide a good institutional environment for solving the financing difficulties of enterprises. Firstly, it should introduce special financing support policies for the medical device industry, strengthen the coordinated linkage of new medical reform policies and financing policies, and introduce corresponding financing support policies in response to the industry impacts brought by the centralized procurement and DRG/DIP reforms, such as establishing special credit subsidy funds for medical device small and medium-sized enterprises, providing interest subsidies to banks for research and development loans and intellectual property pledge loans, reducing the financing costs of enterprises; for small and medium-sized enterprises winning the centralized procurement, establish a special financing guarantee quota to provide low-rate financing guarantee services to solve the working capital needs after winning the bid; for MAH-certified enterprises, introduce special financing support policies to encourage financial institutions to launch special financing products based on MAH certification rights, fully release the policy benefits of the MAH system, and at the same time, incorporate the financing support for medical device small and medium-sized enterprises into the

assessment system for the construction of Healthy China and the high-quality development of the medical device industry, promoting the implementation of relevant policies. Secondly, it should improve the supporting system for intangible asset pledge financing, break through the institutional bottlenecks of intangible asset financing, establish a unified and authoritative intangible asset value assessment system, formulate special assessment standards for medical device patents and registration certificates, cultivate a number of assessment institutions with professional capabilities in the medical device industry, standardize the assessment process, and enhance the credibility of assessment results; improve the intangible asset pledge registration system, establish a unified intangible asset pledge registration platform, simplify the registration process, and improve the registration efficiency, achieving one-stop pledge registration of patents, registration certificates, etc. for intangible assets; broaden the disposal and realization channels of intangible assets, establish a medical device intangible asset trading platform, provide standardized trading and disposal channels for pledged patents, registration certificates, etc., solve the concerns of financial institutions regarding the disposal of intangible assets, and at the same time, establish an intangible asset pledge financing risk compensation fund to provide a certain proportion of risk compensation for bad debts generated by banks in intangible asset pledge financing, enhancing the enthusiasm of banks to carry out related business. Thirdly, it should improve the policy-based financing guarantee system, build a multi-party collaborative risk-sharing mechanism, increase capital injection for policy-based financing guarantee institutions, enhance the guarantee capacity of guarantee institutions, guide policy-based financing guarantee institutions to lower the guarantee rates for medical device small and medium-sized enterprises, cancel the requirement for collateral, and focus the guarantee resources on specialized and innovative medical device small and medium-sized enterprises; Establish a multi-party collaborative risk-sharing mechanism involving "banks, guarantees, insurance, and government". For the financing business of small and medium-sized medical device enterprises, the risks should be shared proportionally by banks, guarantee institutions, insurance companies, and government risk compensation funds. This approach can reduce the risk pressure on a single entity and enhance the willingness of financial institutions to provide credit. Fourth, establish an integrated financing service platform for small and medium-sized medical device enterprises. Connect the "last mile" of policy implementation. Led by the local government, collaborate with the medical insurance department, drug regulatory department, financial regulatory department, financial institutions, and industry associations to build a one-stop service platform integrating policy release, financing connection, compliance guidance, intangible asset operation, and credit evaluation. Timely release the latest medical reform policies, financing support policies, and financial product information to provide policy consultation, financing connection, and compliance guidance services for small and medium-sized enterprises, addressing the information asymmetry issue between enterprises and policies, and financial institutions. At the same time, improve the credit system for small and medium-sized medical device enterprises. Integrate enterprise business registration information, tax information, drug regulatory compliance information, medical insurance centralized procurement information, and bank credit information, establish an enterprise credit evaluation system, incorporate the enterprise's compliance operation status and technological research and development capabilities into the credit evaluation indicators, providing comprehensive credit information references for financial institutions, and resolving the financing predicament caused by information asymmetry. Additionally, strengthen supervision and guidance of the medical device industry, regulate market competition order, severely crack down on unfair competition behaviors, create a fair market competition environment for small and medium-sized enterprises, and increase support for the research and development innovation of small and medium-sized enterprises. Through research subsidies, tax incentives, etc., reduce the research and development costs of enterprises and enhance their core competitiveness, fundamentally solving the financing predicament of enterprises.

6. Conclusion

This study analyzes the financing difficulties faced by small and medium-sized enterprises in China's medical device industry under the ongoing healthcare reform. It identifies key challenges including reduced profitability, constrained financing channels, and mismatches between financing structures and enterprise needs. Through a qualitative policy and industry analysis, the study finds that both institutional and enterprise-level factors contribute to financing constraints. To address these issues, coordinated strategies involving enterprise capability enhancement, financial system innovation, and policy support are proposed. These findings provide practical insights for improving financing accessibility and promoting sustainable industry development.

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