

## Research on the Supply Chain Resilience and Improvement Strategy of National Shortage Drugs

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### Abstract

In view of the implementation of the "Opinions on Promoting the Normalization and Institutionalization of Centralized Drug Purchase with Quantities", the "Key Tasks for Deepening the Reform of the Medical and Health System in 2022", the new version of the "Drug Management Law" and other policies in the pharmaceutical industry, all of which emphasize the vacancy of small drugs (short drugs) in the pharmaceutical market, and it is urgent to focus on the construction of production bases, actively explore the short drugs, and expand the application scenarios, Make up for the blank application of drugs for rare diseases. The supply chain of drugs in short supply is complex. As a kind of medicine supply chain, it is different from the supply chain channel of ordinary drugs. The main reasons are that it is difficult to promote academic research, different policies in different regions, weak production profits and rare raw materials. With the continuous promotion of the two-ticket system, centralized procurement and other policies, risk disturbance factors continue to increase, and the phenomenon of delayed or even interrupted supply of drugs frequently occurs. Therefore, it is necessary to clarify the interference factors and mechanisms that induce the interruption of the supply chain of drugs in shortage, put forward the optimization and promotion strategies for the current market promotion obstacles, accelerate the collaborative cooperation between the government and the market, and provide scientific management suggestions for the prevention, control and treatment of rare diseases. First of all, based on the research contents and achievements of the short supply chain resilience and resilience measurement, starting from the integrity of the supply chain, the particularity and orientation of each member of the chain, this paper conducted semi-structured interviews with senior experts and practitioners, combined with the grounded theory, analyzed and sorted out the interview data collected, extracted indicators by using the open code-spindle code-selective coding, and constructed five first-level indicators 24 secondary indicators of the short supply chain toughness measurement index system, the data model of the coding structure obtained by the saturation test. Secondly, based on the obtained multi-factor interference index, the impact mechanism of supply chain toughness of shortage drugs is further explored, and triangular fuzzy number is introduced. Then, DEMATEL and MICMAC technology are used to draw the antagonism Hass diagram for the interaction and hierarchical relationship of factors, and the hierarchical structure of the directed topological hierarchy formed by the interaction of various factors is analyzed from the result priority level and the cause priority level, which is displayed with visual effect. Finally, by considering and optimizing the factors that interfere with risk treatment and risk treatment costs, an effective optimization model is established to provide reasonable and effective policy improvement suggestions for the comprehensive optimization of supply chain resilience factors of shortage drugs.

## Keywords

**Pharmaceutical Supply Chain; Supply Chain Toughness; Interference Factors; Hierarchical Mechanism.**

## 1. Introduction

For a long time, China and the United States have frequent economic and trade exchanges, and the economic and trade relations of various countries have affected the national economic development pattern. In June 2021, the United States officially released the 100-day supply chain report. In the report, the supply chain resilience system relationship of semiconductors, new energy batteries, rare earth minerals and pharmaceuticals is analyzed. The impact of this report on China is very deep. As early as the trade war from 2018 to 2019, China's biomedical industry showed its advantages. The United States has a huge dependence on China's raw materials and other finished drugs produced by raw materials.

In 2020, the National Health Commission defined 'shortage drugs' as 'drugs that are approved by China's drug regulatory authorities for listing, are clinically necessary and irreplaceable or cannot be completely replaced, and are in short supply or unstable in a certain period of time or a certain area'. However, the definition of shortage drugs in various provinces is not exactly the same. Some provinces further classify shortage drugs, and there are few academic exchanges related to shortage drugs in grassroots reserves. China's modern pharmaceutical industry has a short development time, mostly based on generic drugs, and the level of independent research and development is low. It still relies on the medical level of other developed countries to gradually develop. In the pharmaceutical industry, shortage of drugs is an important guarantee object that cannot be ignored. From the perspective of the attention of developed countries such as the United States to shortage of drugs, the guarantee and supply of shortage of drugs is a major livelihood project, and the causes of supply fracture are complex. Considering the external environment, circulation enterprise process, consignor storage method and distribution management system and other factors, countries put forward different policies to reduce the risk of drug supply chain disruption. Countries such as the Netherlands and Egypt have put forward different policy recommendations in the face of drug shortages in different situations. Drawing on the recommendations and implementation results of many countries, China has promulgated a number of policy documents, and has successively proposed the establishment of a monitoring and early warning and inventory management system for shortage drugs, the implementation of a hierarchical linkage response mechanism, and the precise implementation of shortage drug classification. Focus on drugs that are clinically necessary and irreplaceable or cannot be completely replaced, and there is a risk of supply shortage[1]. Through monitoring and mastering the supply and use of drugs, early warning and timely measures should be taken to prevent shortages.

Resilience is a systematic analysis of the pharmaceutical supply chain. Some scholars first analyzed the current situation of the overall supply guarantee of the pharmaceutical supply chain, and summarized the reasons for the shortage. Some scholars have issued questionnaires or conducted semi-structured interviews to medical institutions, production enterprises, circulation enterprises and health administrative departments, and other channels. Based on the risk assessment of shortage drugs, many factors of supply chain resilience are considered. Domestic research on shortage of shortage drugs collects data from first-line hospitals or medical service centers, and classifies and summarizes the number and frequency of product specifications, causes of shortage, price distribution, dosage forms, whether essential drugs and alternative drug characteristics of shortage drugs. In addition, some studies retrieved Chinese literature related to drug shortage in China from CNKI, Wanfang database and VIP database for many years, and statistically analyzed the publication time, authors, research institutions,

keywords and causes of drug shortage. According to the basic data collected from various channels, the relatively new research in China makes an analysis and comparison before and after the policy from the two aspects of ' list drugs ' and ' non-list drugs ', and concludes that the policy has played a role in curbing the growth trend of the shortage of ' list drugs '. However, it has not curbed the growth trend of the shortage of non-list drugs. From the existing network monitoring, the monitoring of shortage drugs still needs long-term control.

This paper starts from the research on the influencing factors of the supply chain of shortage drugs. Firstly, from the channels of medical institutions, production enterprises, circulation enterprises, etc., semi-structured interviews were conducted with relevant experts and front-line medical practitioners. In view of the different situations of supply chain interruption of shortage drugs, several influencing factors are summarized. Secondly, the influencing factors are coded, and the results are coded by adopting the DEMATEL-MACMIC-AISM joint model.

## 2. Literature Review at Home and Abroad

### 2.1. Research on the Risk of Domestic and Foreign Drug Supply Chain

The supply chain system is complex and changeable, and the risk factors of the supply chain are difficult to define. The main risks come from the internal environment ( risk factors in upstream, midstream and downstream supply chain members ) and the external environment ( economic, political, natural disasters, etc. ). Different scholars analyze supply chain risk from different perspectives. Foreign scholars ' research on supply chain risk begins with the study of supply security. Supply risks are divided into source security, supply security, financial stability and so on. In order to ensure the coordination and stability of the system, scholars have analyzed the drug supply chain from multiple perspectives.

#### 2.1.1. Safety of Drug Source Supply Chain

The source safety problem of the pharmaceutical industry chain supply chain is to provide guarantee for drug quality and safety from drug information traceability as a key part. Drug information traceability refers to tracking and tracing the production, circulation and use of drugs through records and identification [2]. From the perspective of international research results, drug source safety is the focus of national research. Since 2006, the European Federation of Pharmaceutical Industry Associations ( EFPIA ) and the United States FDA have issued " Drug Supply Chain Security Act " and " EU Anti-Counterfeiting Drug Directive " respectively[3]. Based on the bills of drug electronic supervision system in various countries, China proposes to promote drug electronic supervision in stages from special drugs, blood products, essential drugs to full variety classification [4]. Because the electronic supervision of drugs increases the cost of enterprises, the enthusiasm of enterprises for the policy is not high. Based on this, in November 2018, the National Drug Administration ( NMPA ) put forward suggestions for enterprises in terms of drug information traceability standards, information interconnection and data security, and handed over the drug information traceability system to enterprises. Qin Xinsheng put forward the application of Internet of things and RFID technology to develop a unified drug coding system and develop a third-party e-commerce platform in the aspects of drug circulation in drug supply chain management, lagging information system and insufficient logistics service ability [5]. By analyzing the efficacy of RFID technology in the application of supply chain management system, Luo Ruishu established an effective RFID drug supply chain management system to supervise the safety of drug sources [6]. In the context of COVID-19, J. Grumiller et al. evaluated the resilience of pharmaceutical products and global pharmaceutical supply chains, and recommended industrial policies to improve supply security and repatriation, and policies to adjust specific products and product groups to the EU[7]. In order to improve the reliability of data and the accuracy of its distribution in surface technology machine learning, Anitha et al proposed a blockchain-based

security information sharing method LIC-IGL to provide the integrity and security of drug data [8]. A. K. Bapatla et al proposed the third-generation DLT technology based on the problem of counterfeit drugs and generic drugs transported in the global drug supply chain. In the first two generations of DLT technology, consensus protocols such as scalability, transaction costs, power consumption, and transaction speed were added[9]. M. Uddin et al proposed two potential blockchain-based decentralized architectures, Hyperledger Fabric and Besu, to meet the key requirements of drug traceability, such as privacy, trust, transparency, security, authorization and authentication, and scalability, and apply them to several open research challenges related to drug traceability [10]. A. Musamih et al proposed a method based on the Ethereum blockchain, which uses smart contracts and decentralized under-chain storage to ensure data sources, eliminate the need for intermediaries, and enable efficient product traceability in the health care supply chain[11]. The research on drug traceability in China is mainly based on Internet of Things technology, bar code technology, RFID technology, etc. Most of these schemes adopt centralized processing modes such as cloud storage, which are faced with problems such as non-sharing of information, difficulty in traceability, and difficulty in guaranteeing privacy data. Internationally, blockchain technology is used to trace drug information. Blockchain technology has problems such as decentralization, multiple authentication, and transparent interaction. It is the focus of research at home and abroad.

### **2.1.2. Risk of Drug Supply Disruption**

Drug supply management refers to the procurement risk that drugs fail to guarantee supply in all aspects of the supply chain. N. Baporikar et al. In response to the global shortage of drugs, in order to ensure the supply of drugs in short supply, they sent questionnaires to pharmacists and nurses to determine the reasons for the shortage of drugs from the perspective of the supply chain. Finally, they found that supply chain disruption, inefficient management, and insufficient inventory management are the main reasons for the proper delivery and supply of drugs. Difficulties and inefficiency[12]. S. Balestra et al introduced the latest electronic prescription drug monitoring program ( PDMP ) for the tracking of opioids to effectively prevent opioid abuse, treat opioid use disorders ( OUD ) and reduce drug availability. Such detection systems also provide very large supply security recommendations for China 's drug supply.[13]. The domestic procurement method for shortage drugs is mainly centralized procurement. By comparing the production data and agreed data of the winning bid products over the years and following up the actual supply of drugs, Xu Yuan et al provided scientific determination and distribution of procurement volume recommendations to the winning pharmaceutical companies to ensure the production and supply required for centralized procurement [14]. Similarly, in view of the supply problem of centralized procurement, Li Dashuang et al from another perspective, found new problems of rare diseases caused by supply interruption in view of insufficient supply specifications, difficult to meet production capacity and huge price differences among manufacturers[15]. From the perspective of drug withdrawal in recent years, Shen Yan et al proposed that reasonable regulations and norms should be established for the important content of drug price reform, such as provincial bidding rules and withdrawal behavior norms[16]. E. L. Tucker et al believed that estimating the vulnerability of the pharmaceutical supply chain is an important part of improving drug shortages. A reliability model of drug supply chain is proposed. Considering the configuration, risk interruption and recovery speed, the data in this paper are from the main drug shortage database and the data of the case. It is expected to double the recovery speed of the current condition or reduce the interruption rate by half, and put forward the lean configuration of the backup supplier [17]. Qiao Zelin et al proposed the choice of single-source suppliers and dual-source suppliers in the selection of backup suppliers. By analyzing the influence of factors such as the probability of interruption of drug supply and the proportion of order allocation on the

drug collection strategy, Matlab was used for simulation, taking into account the price fluctuation of raw materials and focusing on the stability of continuous supply of drugs [18].

### **2.1.3. Pharmaceutical Supply Chain Financial Security**

Since the study of supply chain disruption, scholars from various countries have proposed solutions to maintain supply chain resilience in many aspects. Among them, most scholars have started from the financial aspect and analyzed independently from the various components of the supply chain to provide a theoretical basis for resisting supply chain risks. In the past decade, supply chain disruptions have affected enterprises in different ways. Z. Liu et al have studied how to take initiatives to mitigate the negative impact on enterprises by optimizing the decision-making order of pricing and hard investment. This research represents most of the current mainstream research directions for ensuring supply chain financial stability[19]. Starting from 2020, large companies such as the United States and Europe are facing huge supply chain risks, and the industrial chain and supply chain have been seriously affected[20]. In order to ensure the consistency of business activities, Lamia Mouloudi et al., starting from the implementation of supply chain risk management, summarized the materials as specific risks, integrated the assessment into supply chain risk management, and established a global framework to provide reference for later scholars[21]. After a targeted study of 856 SMEs in Vietnam, T. Vu et al found that in export-oriented economies, global competition is intense, manufacturing supply chains are inefficient, and there is a lack of supply chain financing products to strengthen links with global supply chains[22]. There are similar studies in China. Considering the uncertainty of the environment and the crisis of trust in the supply chain of small and medium-sized enterprises, the dynamic ability and cooperation level of the supply chain are improved. In view of the current centralized procurement policy in China, Zhang Zhiyong et al combined with the current situation of the development of pharmaceutical circulation supply chain, through the comparative analysis of the two pharmaceutical circulation modes, found that the centralized procurement mode effectively reduced the circulation links and costs, and solved the problem of untimely payment settlement[23]. At present, the financing difficulties of small and medium-sized pharmaceutical production enterprises in China are still the key problems, and the long cycle of reimbursement of pharmaceutical enterprises is still an important difficulty to solve the supply chain interruption [24].

## **2.2. Research and Application of Toughness Theory at Home and Abroad**

### **2.2.1. Concept of Resilience**

In the 1970 s, some foreign scholars began to study the resilience theory. The concept of 'resilience' has undergone two theoretical evolutions, from the field of natural ecology to the field of human sociology, from the initial engineering resilience to ecological resilience[25]. For the first time, Pimm introduced resilience as a characteristic of system stability into the ecosystem and used it as a measure of the speed at which the system regains equilibrium after disturbance[26]. Following previous studies, Holling introduced resilience and stability in ecosystem research, trying to compare engineering resilience and ecological resilience [27]. Peterson et al specially distinguished the two methods and defined stability in two distinct ways : one focused on the efficiency of maintenance function ( engineering elasticity ), and the other focused on the existence of maintenance function ( ecological elasticity ) [28]. Modern supply chain emphasizes that competitors and customers produce customized complex products at low cost, high quality and global customer range, realizes the flexibility of supply chain, and systematically cultivates agility [29]. The rapidly changing market situation, in the case of unstable external environment and continuous crisis, has put the concepts of supply chain resilience and vulnerability that have been neglected in the past at the forefront of supply chain research. These studies have increased people 's awareness of the losses ( direct and

indirect ) caused by supply chain disruptions. The outbreak of COVID-19 has exposed the vulnerability of health supply chains and led to substantial challenges for the entire health system. Snowdon et al. found key characteristics of resilience in health supply chains from seven provinces and municipalities in Canada, providing a positive and comprehensive response to restrict or exclude pandemic management [30].

**2.2.2. Resilience Measure**

The measurement of resilience is mainly divided into quantitative and qualitative analysis. According to the summary of predecessors, the quantitative analysis methods can be roughly summarized into four types : scale / scoring method, index index method, model method and toolkit. The main principles and characteristics are as follows : Table 1, Thurstone, L.L., Likert, R. The two people proposed the Thurstone scale method and the Likert scale method respectively. The Likert scale method is mainly to simplify the Thurstone scale, but the Thurstone scale still plays an irreplaceable role in some fields [31,32]. The index index method is the most popular evaluation system in the field of medical resilience and urban system resilience. Most scholars obtain first-hand data for analysis and evaluation by visiting a large number of professionals. Keller, M.B. proposed the longitudinal interval follow-up evaluation ( LIFE ), and recorded the ordered scale based on the situation in different states [33]. Domestic scholars Hou Kai, Liu Ziyi and others use different scales for different systems for analysis and evaluation [34,35]. The model simulation uses matrix, mathematical function, system dynamics, GIS technology and other methods to stratify the system, and each element interacts with each other [36-39]. In the future, scholars use a variety of algorithms in the computer to iteratively simulate the evolution of the system [40, 41].

**Table 1.** Typical toughness evaluation methods

method	principle	classical principle
Scale method or scoring method	In the form of scales or checklists, respondents were asked to make the most appropriate choice or direct score on resilience-related projects or actions according to their own understanding, and then the number or frequency of different options were counted.	Thurstone, L. L.[31], Likert ,R.[32]
Index index method	A set of quantifiable index system is selected, and then the original data is obtained through structural or semi-structured questionnaire interviews. After processing the original data such as standardization, principal component analysis and analytic hierarchy process, a set of index system is constructed to evaluate and analyze the system, which is also the most popular evaluation tool at present.	Keller, M.B. [33]
model simulation method	The mathematical function and judgment matrix are used to model and analyze the resilience planning scenario. This method simplifies the complex relationship between various risks and resilience-related factors, and approximately describes the complex interaction between resilience multi-dimensional variables.	Chen Weigong et al [36], Huang Jing et al [37], Kong Lingxiao et al [38], He Wengang et al [39]
Tools ( Packages )	Based on computer programs, integrating or combining various methods including index method and model simulation, embedding various algorithms such as neural network algorithm and genetic algorithm, completing the weight distribution of indicators to simulate, evaluate, plan and form suggestions for future resilience scenarios, is the trend of future development.	Renschler, C.S.[40], Xia Chuyu et al[41]

### 2.2.3. Research on Supply Chain Resilience and Supply Chain Measurement

From the definition of supply chain resilience, Christopher and Peck think that the ability of the supply chain to recover to its original state or move to a new, more ideal state after being disturbed is called supply chain resilience [42]. In modern times, Ponomarov and Holcomb attributed the risks and impacts of resilient supply chain management to event preparation and effective response by summarizing previous studies[43]. In the post-epidemic era, a large number of scholars have begun to pay attention to the relationship between efficiency and resilience of global supply chains in the study of 'resilient supply chains'. Gary Gereffi argues that the global trade in various medical products is interdependent in the context of the COVID-19 pandemic[44]. Chad P. Bown also agreed that multinational companies should increase the diversity of supply chains, localize some production in situ, and increase the vulnerability of global supply chains[45]. Between the measurement of efficiency and resilience, we should be vigilant that localization is not equivalent to self-sufficiency, so it is necessary to measure its efficiency and security. Based on the dynamic capability theory, Chowdhury and Quaddus developed the SCRE scale to measure the resilience of supply chain[46]. Considering node failure and demand fluctuation, Xiao et al. constructed a mixed integer programming model with the goal of minimizing the expected total cost of the supply chain system, and verified the effectiveness of the elastic supply chain network optimization model through examples and sensitivity analysis [47]. D'Aguzzo, Lucio argued that stress testing is more effective than direct policy intervention in addressing supply chain rigidities when building resilient supply chains in core strategic sectors[48].

### 2.3. Policy Research on the Resilience of Domestic and Foreign Pharmaceutical Supply Chains

Domestic and foreign scholars generally believe that supply chain resilience in the post-epidemic era should be addressed with more effective and higher-quality trade openness and global supply chain cooperation. Policy research has become the research focus of key product sectors in supply chain resilience research. Grossman, G.M. and other scholars argue that governments should guarantee at least two policies to achieve effective procurement, while subsidizing or taxing outsourcing, and diversifying subsidies from both social and private incentives[49]. Liu Xiangli studied the Japanese government's supply chain resilience policy towards the post-epidemic situation and found that Japan focused on controlling economic losses and controlling risk probability[50]. Baimei's research on the resilience of the EU supply chain found that the EU has strengthened the economic development of industry, exerted the advantages of climate change and digital technology, and gradually formed an industrial ecological model to strengthen the resilience of the supply chain[51]. Snowden, A., et al. found supply chain risks in Canada from decentralized and distributed supply chain management, and proposed that the lack of digital infrastructure and reliance on manual supply chain processes are factors that lead to the fragility of the pharmaceutical supply chain[52]. Nestor, P. advocates that pharmaceutical supply chain manufacturers and suppliers provide free, high-quality training materials, maturity models and resources to identify and mitigate human rights risks[53]. Zhao Yiwei and Liu Honggang believe that the defense supply chain should be targeted from the domestic dual cycle, optimize the industrial structure, financial 'double insurance', digital technology and other aspects to deal with the U.S. supply chain strategy against China [54]. In order to ensure the development of China's supply chain, China and the United States also start from the domestic supply chain, and make policy recommendations from the perspectives of onshore and offshore supply chain, investors' sensitivity to political risks, and adjustment of domestic and foreign economic policies [55].

### 3. Current Problems

At present, the focus of domestic research on shortage drugs includes the shortage of drugs under public health emergencies, the management strategy of drug storehouses, the supply guarantee of essential drugs, and the shortage of drugs in drug procurement. The focus of foreign research on shortage drugs includes the shortage of drugs under public health emergencies, the adverse effects of drug shortage, the shortage of tumor drugs, and the management of drug shortage. Domestic research on the resilience of the shortage drug supply chain mostly starts with subtleties. Scholars generally focus on a certain point in the system, such as finance, channels, profit sharing, etc. Few literatures focus on the analysis of the overall supply chain system. In the study of the pharmaceutical supply chain during the COVID-19, there have been problems of stockouts and medical safety in different situations in various countries. Many scholars have tried to establish some transparent mechanisms from blockchain or information sharing, but resilience should be multifaceted, not just from informationization. At present, China 's economy is developing rapidly, and all walks of life are gradually entering digitalization. The pharmaceutical industry is gradually separated from the traditional pharmaceutical model. The digital innovation of medicine is no longer limited to a certain link and a certain technology, but stands in the overall perspective of the industrial chain, the whole process, a number of technical integration of common innovation. From the perspective of the entire pharmaceutical system, this paper considers the disruption risk from the industrial chain to the supply chain through in-depth analysis of the pharmaceutical supply chain system. The following are new issues that may need to be considered.

(1) From the perspective of pharmaceutical manufacturing. The pharmaceutical manufacturing field is mainly divided into pharmaceutical raw material supply, pharmaceutical research and development, and pharmaceutical production. From the perspective of the supply of pharmaceutical raw materials, the generation of raw materials ranges from the planting of medicinal materials to the price of raw materials. The raw materials mentioned by scholars belong to the original drug, generally referring to the raw materials after processing. The shortage problems of a large number of shortage drugs include increasing production and improving quality, natural risks, price fluctuations and supply fluctuations. In the case of monopoly of pharmaceutical raw materials, the main reason is that the shortage of raw materials leads to the interruption of the manufacture of shortage drugs. Pharmaceutical research and development is divided into early research and development, preclinical research and clinical research. The process includes disease selection, target discovery, compound synthesis, compound screening, crystal prediction, process management, and data analysis. R & D takes the longest time and the process is complex, but the main interruption factor is not this. Pharmaceutical production is divided into approval of listing, production supply chain, drug production. The main reasons for drug cards in the production process are time-consuming approval, supply chain integration, process management, raw material management and quality supervision. This part is the focus of the pharmaceutical manufacturing process, the main guarantee is the final preparation before the drugs flow into the market.

(2) From the perspective of pharmaceutical circulation. The field of pharmaceutical circulation is divided into pharmaceutical commerce, pharmaceutical marketing and pharmaceutical services. Pharmaceutical business is divided into drug transportation, drug supervision and distribution. The problems include inventory management, safety tracking, cold chain transportation, transportation safety, logistics management, prescription outflow and so on. Pharmaceutical business is mainly to ensure the source and destination of drugs, in an intermediate link after manufacturing. Pharmaceutical marketing from distribution channels to marketing to doctor services, its sales clearly show the circulation of drugs. The main



problems are drug support medicine, medical representatives, channel optimization process, rare clinical data, complex patient management, academic conferences, and professional promotion. The last link is medical services, that is, the end of the field of pharmaceutical circulation. From medical inquiry to medication consultation, the last is medication management. The main problems are patient service, medication experience, medical insurance reimbursement, medication safety, prescription review, and mobile medical care.

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