

Research on the Legal Issues of the Compulsory Liability Insurance System for Drug Safety

Yidan Dong

School of International Pharmaceutical Business, China Pharmaceutical University, Nanjing,
China, 211198

dongyidan@stu.cpu.edu.cn

Abstract. As an important legal tool in the field of drug safety, the role of the compulsory liability insurance system for drug safety is mainly to regulate various risks in the field of drug safety through the precautionary principle, and at the same time, it is also to fully protect the legitimate rights and interests of relevant patients to receive timely relief due to drug damage. Through the theoretical review of previous studies, it can be seen that there are still relevant deficiencies in the compulsory liability insurance system for drug safety. Based on this, this paper intends to innovate and improve it from the following paths, and strive to give full play to the original utility of the system: reinterpret the conceptual connotation of the compulsory liability insurance system for drug safety, analyze the new application mode of public compulsory liability theory and market failure theory in the field of drug safety, learn from the good experience of typical countries in the field of drug safety, and then improve the compulsory liability insurance system for drug safety. To improve the compulsory liability insurance system for drug safety, it is necessary to clarify the basic concept of drug damage, clarify the scope of application and the reasons for exemption, analyze the role and operation mechanism of the insurance subject, and construct the insurance rate system and the division of liability, so as to achieve the most ideal effect.

Keywords: Drug Safety, Compulsory Liability Insurance, Legal Regulation.

1. Introduction

The drug safety compulsory liability insurance system has two complementary functions: on the one hand, it protects the personal and property rights of medical patients by means of legal regulation; on the other hand, it regulates the risks related to the production, operation and use of drugs, so as to achieve the dual goals of drug safety and risk management, aiming to improve the safety level of the pharmaceutical industry. By searching and sorting out relevant literature, it can be learned that there are still some deficiencies in the theoretical and practical research on it in the academic community.

The existing research arguments are mainly reflected in the following aspects: Li Xiaolin and Jiang Chenxia scholars have conducted in-depth discussions on the current status and challenges of China's production safety liability insurance, and put forward corresponding improvement measures and suggestions, providing theoretical support and practical guidance for further promoting the healthy development of the pharmaceutical industry [1]; Zhao Yixuan and Lin Hongchao scholars have discussed the functional transformation and system improvement of production safety liability insurance, providing reference for the effective regulation of public risks and the transformation of compulsory drug safety liability insurance [2]; Luo Jingshu and Grace Martin F. scholars have conducted in-depth analysis of the impact of the expansion of the Medicaid program on the price of physician liability insurance, revealing the potential connection between the expansion of public health insurance and the cost of medical liability insurance [3]; Lebihan Laetitia scholars have provided important ideas for the optimization of drug policies in the public health system by studying the impact of compulsory drug insurance on health behaviors [4].

Overall, the existing literature has conducted pioneering research on the drug liability insurance system, but there are still some deficiencies in some issues, and relevant solutions are urgently needed. Through the interpretation of the connotation of compulsory drug safety liability insurance and related basic theories, the existing typical countries' compulsory drug safety liability insurance system is analyzed, and a sound path for the relevant content of compulsory drug safety liability insurance is

proposed, in order to promote the improvement and development of the drug liability insurance system and provide strong support for promoting the high-quality development of the pharmaceutical industry.

2. Basic research related to the compulsory drug safety liability insurance system

2.1. Conceptual Research

The insurance system is a mechanism that disperses risks and provides economic security by collecting premiums, and the compulsory drug safety liability insurance system is an insurance that the drug marketing authorization holder (MAH) must enter into a liability insurance contract with the insurer in accordance with national laws. Some scholars believe that compulsory drug safety liability insurance is an important risk management tool that manages risks and provides economic compensation for damages that may be caused by drug defects [5]; some scholars believe that compulsory drug safety liability insurance belongs to the category of liability insurance, in which MAH, as the insured, pays the necessary insurance premiums. If the patient is harmed due to quality problems after the drug is launched, the insurance company will compensate the civil compensation liability borne by MAH within the liability limit [6].

The drug safety compulsory liability insurance studied in this article is one of the compulsory insurance types in which the drug marketing license holder pays insurance premiums to the insurance company as the insured to ensure that when there are problems with the drug quality, financial compensation can be made to the damaged users in accordance with the law. It should be clear that drug safety compulsory liability insurance has its own unique characteristics:

First, compulsory drug safety liability insurance has obvious mandatory characteristics. This insurance is mandatory for drug marketing license holders to purchase in order to ensure the safety of public drug use. General drug safety liability insurance is a more extensive and voluntary liability risk protection method, which covers various civil legal risks that may cause property loss or personal injury to others. It is usually not mandatory, but is purchased voluntarily according to the needs of the insured.

Secondly, compulsory drug safety liability insurance usually has a specific coverage. For example, compulsory vaccine liability insurance is mainly aimed at damage to vaccine recipients caused by vaccine quality problems, while commercial drug insurance is a more extensive insurance product based on market demand and voluntary principles. Its coverage includes risks in various links of drug research and development, production, and sales. The specific coverage content can be determined according to the terms of the insurance contract.

Finally, compulsory drug safety liability insurance focuses more on post-event protection. Compulsory drug safety liability insurance is mainly aimed at protecting public health after the drug is launched on the market, while drug clinical trial liability insurance focuses on protecting the rights and interests of subjects during the clinical trial stage. For example, during the clinical trial of a new drug, if the subject suffers from serious adverse reactions caused by the drug, including drug side effects, allergic reactions and other health problems, the insurance company will provide financial compensation to the subject according to the terms of the insurance contract.

2.2. New interpretation of the theory

The theory of public coercion mainly discusses how the state or government can intervene and regulate public affairs through legal and administrative means to ensure social order and public interests. The theory believes that in some cases, the market mechanism cannot effectively solve public problems, and the government needs to intervene through compulsory measures to achieve the rational allocation of resources and maximize social welfare. [7] In the fields of life and health, public

construction, etc., the government restricts the behavior of individuals or enterprises to protect the public interest by formulating and enforcing relevant laws and regulations.

The theory of public compulsion provides a theoretical framework for the medical field, emphasizing the core role of the government in formulating and enforcing relevant laws and regulations on drug management: on the one hand, the government supervises the entire process of drug research and development, production, circulation, and sales through a strong supervision and enforcement mechanism to ensure that the entire life cycle of drugs meets national safety standards. On the other hand, by formulating mandatory standards and risk management plans, the risks in the use of drugs are reduced to protect the health rights and interests of patients. The state or government requires MAH to insure marketed drugs through legal provisions, which not only ensures that consumers can receive timely and effective compensation when encountering drug quality problems, but also encourages pharmaceutical companies to strengthen risk management and product quality control through economic incentives.

Market failure theory is an important theory in economics used to explain the existence of non-profit organizations. It believes that market failure occurs when the market mechanism cannot effectively provide goods and services under certain circumstances, or cannot provide economically optimal services, at this time, the intervention of the government or non-profit organizations is needed to fill the gap left by the market [8]. Due to the professionalism and complexity of the pharmaceutical market, market failure is particularly prominent in this field: on the one hand, there is significant information asymmetry between consumers (patients and doctors) and suppliers (pharmaceutical companies) in the pharmaceutical market; This makes it difficult for consumers to fully evaluate the safety and effectiveness of drugs, thereby affecting the quality of market decisions. On the other hand, the market may not provide sufficient incentives for drugs that are important to public health but have low commercial profits. For example, drugs to treat rare diseases are often ignored by pharmaceutical companies due to their limited market size.

In order to solve the above-mentioned market failure problem, the introduction of compulsory drug safety liability insurance can be used as a solution. This insurance system requires MAH to insure the damage that may be caused by its marketed drugs, providing consumers with a certain degree of risk protection. In this way, the externalities caused by market failure can be internalized, so that pharmaceutical companies will pay more attention to the safety of drugs during the research and development and production process, because once there is a problem with the drug, the pharmaceutical company needs to bear the corresponding economic responsibility. This potential cost pressure will encourage them to invest more resources in drug safety.

3. Relevant practices and experiences of drug safety relief systems in typical countries

3.1. Germany: Drug safety guarantee system under no-fault liability and liability limit

Germany's drug regulatory agencies mainly include the Federal Drug and Medical Devices Agency and the Federal Vaccine and Serum Institute, which are responsible for the regulation of medical devices and human drugs and the regulation of special drugs such as serum and vaccines. A key area of German drug regulation is the regulation of anthropological drugs. The results of the study showed that the frequency of adverse drug reaction reports for all AMPs from 2010 to 2017 was 1.50 times per million maximum daily doses, of which the frequency of serious ADRs was 0.03 times per million MDADs. Most patients have recovered or are recovering from ADRs, and there are no reports of ADRs with fatal results [9]. This shows that Germany's drug regulatory system plays an important role in ensuring drug safety, and also reflects the importance of post-marketing monitoring of drugs.

At the same time, Germany's drug safety insurance system provides additional protection for drug safety, requiring drug marketing authorization holders to purchase commercial insurance or provide financial guarantees to protect their compensation capabilities. In addition, the system embodies the core principle of Germany's drug damage liability system - no-fault liability, that is, regardless of

whether the pharmaceutical company is at fault, once the drug is defective and causes damage to the patient, the company must bear the corresponding compensation liability. In addition, in order to balance the company's ability to bear and protect the legitimate rights and interests of the victims, Germany has set an upper limit on drug damage compensation, including the maximum compensation amount for each incident and the upper limit of the total compensation amount. This provision not only prevents companies from falling into financial crisis due to facing huge compensation, but also ensures that victims can obtain fair and reasonable compensation.

3.2. Japan: Drug adverse reaction relief mechanism under the fund model

Japan's drug safety information communication system is relatively complete, with the Ministry of Health, Labor and Welfare and other agencies responsible for implementing drug safety policies and dealing with issues directly related to public life and health. The above agencies communicate drug risks through various forms such as documents, drug instructions, notices, professional websites, etc., to ensure that drug safety-related information is disclosed and disseminated in a timely and effective manner [10].

The legal mechanism for regulating drug safety in Japan is the adverse drug reaction relief mechanism, which is mainly a fund model and is managed by the Pharmaceutical and Medical Device Agency (PMDA) of the Ministry of Health, Labor and Welfare. After patients follow the doctor's advice or prescription to use drugs, if serious adverse reactions occur and the legal liability and responsible subject of the drug are unclear, the victim can apply to the government for a relief fund to ensure that the victim can get reasonable economic compensation [11]. Specifically, it is reflected in the following aspects: First, the government's credibility is used as a guarantee. The mechanism is operated by PMDA, which not only ensures the timeliness and fairness of the relief measures, but also improves the transparency and credibility of the compensation through the scientific decision-making of professional institutions, fully demonstrating the government's positive role and responsibility in drug safety supervision; secondly, the relief subjects are diversified. The mechanism covers all individuals who are harmed by adverse drug reactions (not limited to specific drugs or groups) and provides victims with a clear relief channel. Regardless of whether the legal liability of the drug is clear, the victim can get timely economic compensation. Finally, as a supplementary mechanism, it helps to build a drug safety supervision system. This mechanism collects and analyzes data related to adverse drug reactions, thereby complementing the post-marketing monitoring and evaluation system for drugs, and jointly promoting the improvement of Japan's drug safety regulatory system.

3.3. China: Combination of mandatory public welfare and pluralistic governance model

China is gradually establishing and improving the insurance system related to drug safety, which reflects China's high attention to drug safety issues. In recent years, the China National Center for Adverse Drug Reaction Monitoring has further increased its monitoring efforts and comprehensively promoted the construction of monitoring systems and capabilities. By comparing the number of "Adverse Drug Reaction/Event Report Forms" received by the National Center for Adverse Drug Reaction Monitoring in 2022 and 2023, it can be seen that a total of 2.419 million reports were received in 2023, an increase from 2.023 million in 2022. This not only shows that the coverage of drug safety monitoring is wider, but also reflects that the public and medical institutions are aware of the improvement of reporting of adverse drug reactions. In addition, in terms of new and serious adverse reaction/event reports, 833,000 reports were reported in 2023, accounting for 34.5% of the total reports, while the number in 2022 was 642,000, accounting for 31.7% of the total reports, which also showed an upward trend, further highlighting the urgency and importance of drug safety supervision [12, 13].

This growth trend reflects the significant progress in the identification and reporting mechanisms of China's adverse drug reaction monitoring system: on the one hand, the increase in the number of reports shows the expansion of the coverage of the monitoring system, which means more medical

institutions and drug use links. Being included in the monitoring network has improved the identification rate of drug safety issues; on the other hand, it reflects the increased awareness of the public and medical institutions on adverse drug reaction reporting, providing drug regulatory agencies with richer data resources to support their formulation of more effective regulatory strategies and interventions.

It is worth noting that China's drug safety compulsory liability insurance system is unique. It combines the characteristics and needs of the domestic drug market and provides more comprehensive risk management measures for drug production, circulation and use. It is mainly reflected in the following points: First, it is characterized by public welfare and mandatory nature. The public welfare is mainly reflected in the insurance mechanism, which ensures that patients using drugs can obtain compensation in a timely manner and maintain social stability and public health rights. The mandatory nature is reflected in the state or government requiring drug marketing license holders to purchase drug safety compulsory liability insurance through laws and regulations, so as to ensure that drug safety risks are effectively managed and controlled. Secondly, the risk prevention mechanism of the whole process. Through the insurance mechanism, the risk awareness and management level of drug production and operation enterprises are improved to prevent the occurrence of drug safety accidents. Finally, the multi-governance governance model. Drug safety regulation emphasizes social co-governance, including the joint participation and collaborative governance of multiple subjects such as the government, the market and society, so as to build a more sound, transparent and efficient drug safety management system.

4. The path to improve the legal system related to the compulsory drug safety liability insurance system

4.1. Clarify the inner meaning of drug damage

From a legislative perspective, "drug damage" is a legal concept that comprehensively considers the relationship between drug use and health effects. First, it is necessary to determine the correlation between drugs and damage, that is, the damage must be directly related to the use of drugs; secondly, the certainty of damage is the core element in the definition, and the damage must actually occur and have identifiable medical symptoms or health effects; finally, the existence of a causal relationship is a key element in determining drug damage. There must be sufficient medical evidence to prove that the root cause of the damage stems from the use of specific drugs to ensure the accuracy of liability attribution. And in legislative practice, different countries have different provisions on the relevant legal provisions for drug damage. The German "Drug Law" emphasizes the strict liability of pharmaceutical companies. When a patient suffers physical damage after using a drug as prescribed by a doctor, and the company cannot prove that the damage is unrelated to its drug, it must bear the corresponding responsibility [14]; Japan's definition of drug damage focuses on health damage caused by adverse drug reactions, such as serious physical injuries or diseases caused by drug side effects; China is more concerned about the damage caused by drug quality defects. According to the "Regulations on Pharmaceutical Management of Medical Institutions", drug damage refers to the damage to patients caused by drug quality not meeting national drug standards. In summary, the meaning of drug damage from a legislative perspective can be summarized as: damage caused by taking specific drugs with clear medical evidence, and the damage must have a causal relationship with the use of the drug.

From the perspective of academic research, scholars have different perspectives and understandings on the concept of drug damage. Some scholars focus on adverse drug reactions, and divide them into different degrees of reactions, ranging from mild injuries to severe systemic injuries, according to the severity of the damage [15]; some scholars pay more attention to the legal and ethical aspects of drug damage, and explore the issues of liability and compensation for drug damage [16]. It should be made clear that the drug damage discussed in this article refers to direct physical injuries

or potential health risks suffered by medical patients due to the pharmacological properties of drugs or other external factors.

From a practical perspective, drug damage can be divided into two different life cycles: pre-market and post-market, and each cycle may produce different types of damage. Before a drug is marketed, damage can be divided into two main categories: predictable damage and unexpected damage. Predictable damage usually stems from human factors, such as the failure of a drug to meet expected quality standards due to negligence or errors by researchers during drug development and production. Unpredictable damage stems from the limitations of scientific and technological levels. The potential risks of some drugs may only gradually emerge after the drug is marketed, bringing unknown health threats to patients. After a drug is marketed, damage mainly includes the following three situations: First, incorrect use of qualified drugs. That is, the drug itself is of qualified quality, but due to improper operation by medical professionals or patients during use, the patient suffers damage. Second, adverse reactions that occur during the normal use of qualified drugs. When the drug is used correctly, patients may still experience adverse reactions due to individual differences or the inherent characteristics of the drug. Third, drug safety risk management issues. After a drug is marketed, drug safety risks are not discovered in a timely manner due to insufficient risk assessment or lax supervision.

4.2. Clarify the relevant scope of application and grounds for exemption

At the international level, different countries have different types and coverage of drug insurance systems. Germany's coverage does not distinguish between types of drug damage, but only covers situations that cause serious injury or death; the United States uses voluntary insurance to reduce product liability risks, and its coverage covers all types of claims caused by drug side effects or defects; Japan's fund model mainly provides relief for patient damage caused by adverse drug reactions; China's compulsory drug safety liability insurance covers issues such as adverse drug reactions and drug defects. The above international practices reflect the adaptive choices made by various countries based on the characteristics of their own pharmaceutical markets and legal backgrounds. Although the contents vary, all countries focus on the damage caused by drug quality issues, which shows that drug quality is the core element of the compulsory drug safety liability insurance system.

This article believes that the core of compulsory drug safety liability insurance is to provide medical patients with protection against damages caused by drug quality problems. Its coverage should be limited to the quality problems of the drug itself, excluding damages caused by personal improper use or intentional illegal acts. For example, foreseeable problems caused by human factors or improper management during the drug research and development and production process, as well as incorrect use of qualified drugs due to unclear drug instructions. In the above cases, drug quality problems are the direct cause of the damage, and therefore fall within the scope of protection of compulsory liability insurance. In addition, the insurance also covers damages caused by insufficient drug risk management, such as failure to identify and report drug risks in a timely manner, or damages caused by poor implementation of recall measures.

It should be clear that in certain specific circumstances, the insurance company can be exempted from the relevant compensation liability, which is specifically manifested as follows: First, force majeure factors. Force majeure usually refers to external events that are unforeseeable, unavoidable and insurmountable [17], and have a substantial impact on the performance of the contract. Since such events are beyond the control of the insurance company, the insurance company is usually not responsible for compensating the losses caused thereby. Second, the intentional behavior, gross negligence or illegal behavior of the insured. When the drug damage is caused by the insured's improper behavior, the insurance company shall not bear the compensation liability. For example, if the drug damage incident occurs due to gross negligence during the production or sales of drugs, the insurance company will not compensate. This reflects the principle of fairness of the insurance contract, that is, to protect the balance of interests of both parties to the insurance and avoid moral risks [18]; Third, improper use of drugs by users. If the user fails to follow the doctor's advice or the

instructions of the drug instructions and misuses the drug and causes injuries or losses, the insurance company will also not bear the compensation liability. For example, if the patient does not take antibiotics according to the doctor's prescribed dosage, resulting in a serious drug allergic reaction, the insurance company will not compensate for the resulting medical expenses or other losses.

4.3. Analyzing the roles and operating mechanisms of insurance entities

The subjects involved in the compulsory drug safety liability insurance system mainly include the policyholder, the insured and the insurer. Usually the policyholder and the insured are the same person, namely the MAH. In some cases, the policyholder and the insured are not the same person, which mainly manifests in the following two situations: one is group insurance. If a pharmaceutical group company uniformly insures the compulsory drug safety liability insurance for its multiple subsidiaries or affiliated companies, the group company is the policyholder, and each subsidiary or affiliated company is the insured. The second is an agency or entrustment relationship. MAH can entrust a third party (such as an agent or distributor) to insure on its behalf, then the third party is the policyholder and MAH is the insured.

Compulsory drug safety liability insurance can not only reduce the transaction costs of MAHs due to agency problems [19], but also enable MAHs to avoid compensation liability due to drug quality issues through a risk transfer mechanism. In addition, as a mature compulsory insurance system, the basic premium of compulsory motor vehicle traffic accident liability insurance (compulsory traffic accident insurance) is set according to different vehicle types, thereby reflecting the inherent risk differences of various types of vehicles. When promoting the compulsory drug safety liability insurance system, the terms of compulsory traffic accident insurance cannot be mechanically applied, but the particularity of the pharmaceutical market must be fully considered to ensure the applicability and effectiveness of the insurance system. Therefore, when determining the scope of choice for the insured, the market share, economic strength and other factors of the MAH should be comprehensively evaluated.

In the research field of compulsory food safety liability insurance, some scholars have proposed two models for the generation of insurers: one is the regulatory agency setting model, in which the regulatory department directly designates insurance service providers; the other is the insurer's active application approval model, which allows insurance companies to apply independently according to established standards and pass the approval of the regulatory agency [20]. Based on an in-depth analysis of these two models, this paper makes adjustments and optimizations based on the characteristics of the pharmaceutical industry. Therefore, a new model for the generation of insurers, the collaborative insurance model, is proposed, which aims to achieve an effective combination of government supervision and market mechanisms to promote the healthy development and fair competition of the drug safety liability insurance market.

The basic framework of the collaborative insurance model is designed as follows: First, it emphasizes the core position of the government. The government has established the legal basis for compulsory drug safety liability insurance through legislation, and defined its service scope, quality standards and compensation procedures. In addition, the government has taken the lead in establishing a qualification certification system, stipulating that only insurance companies that meet specific standards can enter the market to provide services. Secondly, in the early stages of the development of the insurance market, the government will designate or authorize some insurance companies to provide services to promote the rapid growth and stability of the market.

As the market matures, it will be transformed into a regular open bidding mechanism to attract new insurance companies to participate in the competition and promote the continuous innovation and optimization of insurance products and services. Finally, a risk-sharing mechanism will be established. Risks can be dispersed by developing the reinsurance market or creating a cooperation platform to maintain the stability and sustainable development of the insurance market. The advantage of the collaborative insurance model is that it effectively balances government supervision and market mechanisms and accelerates market development through moderate government

participation. The limitation of this model is that it requires a high level of government supervision capabilities, and when it is implemented in different regions, it needs to be adjusted accordingly according to local market conditions and regulatory environment.

4.4. Improve the insurance premium rate system

The rate design of compulsory drug safety liability insurance can refer to the experience of compulsory vaccine liability insurance, and should be designed mainly from two aspects: drug risk level and corporate credit rating.

The assessment of drug risks involves multiple factors such as the incidence, severity and frequency of adverse drug reactions. Therefore, when designing the rates for compulsory drug safety liability insurance, the risk differences of different drug categories should be fully taken into account. Drug categories are mainly divided into three categories: chemical drugs, traditional Chinese medicines and biological products. According to the 2023 drug adverse reaction/event report, chemical drugs have the highest number of adverse reaction reports, accounting for 81.2% of all drug categories [21]. Among them, the number of adverse reaction reports for anti-infective drugs is particularly prominent, followed by oncology drugs and cardiovascular system drugs. Therefore, higher insurance premiums need to be set for chemical drugs to reflect their higher adverse reaction reporting rate and the serious consequences that may be caused.

Compulsory traffic insurance implements a floating rate mechanism linked to the credit rating of the vehicle driver. This mechanism reflects the risk level of different drivers based on factors such as the driver's traffic violation record and accident responsibility. Drawing on the credit rating system of compulsory traffic insurance, compulsory drug safety liability insurance can also introduce a similar mechanism to include the insured's credit rating in the consideration of insurance premiums. It is worth noting that the products and services of the pharmaceutical industry are directly related to public health and safety, so the practice of corporate social responsibility (CSR) can be used as a core element in assessing the credit rating of pharmaceutical companies [22].

Based on this, a pharmaceutical enterprise credit rating evaluation mechanism with CSR as the core can be constructed, which will comprehensively evaluate the performance of pharmaceutical enterprises in many aspects. Among them, product quality and safety are the core of the evaluation mechanism. When evaluating, the production standards, quality control processes, and the degree of perfection of the product recall mechanism of the enterprise can be considered. At the same time, the investment and results of the enterprise in new drug research and development or treatment methods can also be used as indicators to measure its long-term development potential and fulfillment of social responsibility. In addition, the compliance of pharmaceutical enterprises is also one of the criteria for evaluating their credit ratings.

Through the comprehensive evaluation of the above aspects, companies with higher credit ratings can enjoy lower insurance premiums, while companies with lower credit ratings need to pay higher insurance premiums. This mechanism aims to fully reflect the credit status of pharmaceutical companies, thereby affecting the level of insurance premiums, encouraging companies to make more efforts in social responsibility, and improving the safety and credibility of the pharmaceutical industry.

5. Conclusion

This article deeply analyzes the theoretical basis and international practice of the compulsory drug safety liability insurance system, and proposes a sound path and innovative model, aiming to improve the level of drug safety, protect the rights and interests of medical patients, and promote the high-quality development of the pharmaceutical industry through the combination of legal regulation and market mechanism. It should be pointed out that there are still some unfinished parts in this article, which also need to be further explored. Future research can further study the regional adaptability of the system and its impact on regulatory policies to provide more accurate data support and strategic recommendations.

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