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International Risk Early-Warning System Construction and Application for International Pharmaceutical and Chemical Trade: An Empirical Analysis Based on Multi-Source Data Fusion and LSTM-PSO Algorithm

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Abstract

International pharmaceutical and chemical cross-border trade is characterized by high compliance requirements, significant market volatility, and long supply chain links. Small and medium-sized foreign trade enterprises (SMEs) generally face the pain points of unpredictable compliance risks, lagging market responses, and insufficient supply chain early warnings. To address these issues, this study focuses on four core risks: compliance, market, supply chain, and credit. A four-dimensional risk assessment framework comprising 23 indicators is constructed. By integrating multi-source data from policies, markets, and enterprises, and optimizing the key parameters of the Long Short-Term Memory (LSTM) network using the Particle Swarm Optimization (PSO) algorithm, an intelligent risk early-warning system based on the LSTM-PSO algorithm is established. An empirical analysis is conducted using the cross-border trade data of Wuhan Kuda Hui Trading Co., Ltd. from 2019 to 2024. The results show that the model achieves a high-risk event early warning accuracy rate of 92.3%, and the lead time for logistics delay risk early warning is extended to 168 hours. After the system is implemented, the incidence of high-risk events in the enterprise decreases from 15.6% to 4.8% (Benamor, W. D., 2022), and in 2024, a loss of 2.16 million yuan is avoided. Moreover, the relevant solutions have been promoted to 12 enterprises in the industry, with an average reduction in risk losses of 37.2%. The study confirms that the LSTM-PSO risk early-warning system can effectively enhance the risk prevention and control capabilities of SMEs in the pharmaceutical and chemical foreign trade sector and has significant practical application and industry promotion value.

Keywords: pharmaceutical and chemical trade, cross-border trade, risk early-warning system, multi-source data fusion, LSTM-PSO algorithm, risk indicator system, SMEs, empirical analysis

1. Introduction

1.1 Research Background and Problem Statement

International pharmaceutical and chemical trade combines the complex compliance of chemical products and the strict regulation of pharmaceutical products. The industry is characterized by high compliance requirements, significant market price volatility, and long supply chain links. These characteristics expose SMEs to significant risks in international competition, including dynamic regulatory policies, fluctuations in raw material prices and exchange rates, uncertainties in cross-border logistics, and supplier performance. Traditional risk early-warning methods, which rely on manual experience or single data sources, are unable to meet the dynamic and multi-dimensional needs of cross-border trade. They often respond passively after risks have occurred. Wuhan Kuda Hui, with its rapidly growing trade scale, has insufficient risk prevention and control capabilities and has

suffered losses multiple times due to regulatory updates, logistics delays, and price fluctuations. There is an urgent need for risk prevention and control.

1.2 Research Objectives and Significance

This study aims to address the industry pain points from both theoretical and practical perspectives. Theoretically, it aims to improve the construction of the risk early-warning indicator system for pharmaceutical and chemical trade, enrich the application of deep learning algorithms, and fill the research gap on the adaptability of risk early-warning algorithms for SMEs. Practically, it focuses on the needs of SMEs to develop a low-cost, high-precision risk early-warning solution, helping enterprises to identify risks in advance, reduce losses, and enhance their international market competitiveness.

1.3 Core Research Positioning and Innovations

This study focuses on three core risk types: compliance, market, and supply chain. It integrates multi-source information to construct an intelligent risk early-warning system based on the LSTM-PSO algorithm and validates it using the data of Wuhan Kuda Hui from 2019 to 2024. The innovations include: (1) constructing a four-dimensional, 23-indicator risk indicator system tailored to the SME scenario; (2) using the PSO algorithm to optimize the parameters of the LSTM network, improving the accuracy and timeliness of early warnings; and (3) applying the system to an actual enterprise and forming a replicable industry risk prevention and control solution, achieving a closed loop from theory to practice.

2. Construction of Risk Indicator System for Pharmaceutical and Chemical Trade

2.1 Design Principles of the Indicator System

The risk indicator system is the core foundation for the effective operation of the intelligent early-warning system. The quality of its design directly determines the accuracy and practicality of risk early warnings. Therefore, this study strictly follows three core principles in constructing the indicator system: scientificity, operability, and timeliness. The principle of scientificity requires that indicators accurately reflect the essence of risks in international pharmaceutical and chemical trade and fit the business logic and risk exposure characteristics of SMEs. It avoids simply copying the indicator framework of large multinational corporations, ensuring that each indicator corresponds to specific risk points in the actual trade process. The principle of operability emphasizes that all selected indicators must have accessible and quantifiable data. Relevant data can be obtained from internal trade records, financial statements of enterprises, industry databases, government public platforms, and third-party information agencies. It avoids the inclusion of abstract and unimplementable indicators. The principle of timeliness targets the dynamic nature of risks in pharmaceutical and chemical trade, ensuring that indicators can reflect the latest status of policy updates, market fluctuations, and supply chain adjustments in real-time. It meets the fast response requirements of cross-border trade and effectively avoids early-warning failures due to indicator lag. These three principles support each other and are all essential, jointly ensuring that the indicator system is both theoretically logical and practically applicable for risk early-warning in SMEs.

2.2 Core Risk Indicator Settings in Four Dimensions

Based on the risk characteristics of international pharmaceutical and chemical trade and the actual pain points of SMEs, this study constructs a core risk indicator system covering four dimensions: compliance, market, supply chain, and credit. Differential weights are assigned to each dimension according to its impact on trade losses. Compliance risk, the primary risk in pharmaceutical and chemical trade, accounts for 35% of the weight and includes 10 core indicators that comprehensively cover the regulatory compliance risks faced by enterprises in cross-border trade. These indicators include the frequency of target market regulation updates, product certification validity period, customs inspection rate, cross-border environmental compliance requirements, intellectual property infringement risk, import and export license processing cycle, tax compliance verification frequency, anti-dumping investigation early-warning index, labor compliance requirements, and data cross-border compliance. Market risk, with a weight of 25%, includes five core indicators focusing on key market fluctuation risks, such as the price volatility rate of core products, exchange rate fluctuation amplitude, raw material supply gap rate, market demand forecast deviation rate, and competitive product price impact coefficient. For example, the price volatility rate of core products like Norfloxacin, the main product of the enterprise, can be intuitively reflected by the monthly price variation coefficient, accurately showing the impact of market price fluctuations on trade profits. Supply chain risk, with a weight of 30%, includes six core indicators targeting the long supply chain links and multiple links in pharmaceutical and chemical cross-border trade. These indicators involve supplier performance rate, logistics delay rate, warehouse turnover rate, geopolitical impact coefficient, port congestion index, and supply chain node interruption probability. Credit risk, with a weight of 10%, includes two core indicators focusing on the core risks in the capital settlement link of cross-border trade, namely customer payment overdue rate and third-party credit rating changes.

2.3 Indicator Quantification and Standardization

The effective application of the indicator system relies on unified quantification and standardization. For qualitative and quantitative indicators with different attributes, this study adopts different processing methods. For qualitative indicators that cannot be directly quantified, such as the geopolitical impact coefficient, an expert scoring method combined with event value assignment is used for quantification. Industry experts and front-line practitioners in the field of pharmaceutical and chemical trade are invited to score the impact of different geopolitical events (such as strait navigation risks, trade sanctions, regional policy adjustments, etc.) on the trade chain. The scores are then calibrated with the actual trade loss data of enterprises after the events occur to convert abstract risk descriptions into computable values. For quantitative indicators such as core product price volatility rate and exchange rate fluctuation amplitude, the Z-score standardization method is used to eliminate the differences in units of different indicators. All indicators are unified into the same range to avoid weight imbalances caused by different units. This ensures that each indicator can fairly participate in the early-warning model calculations, improving the accuracy and reliability of the model from a data perspective.

3. Construction of the Risk Early-Warning Model Based on LSTM-PSO

3.1 Preprocessing of Multi-Source Data

The effective integration of multi-source data is a prerequisite for the practicality of the risk early-warning model. The data sources collected in this study cover three dimensions: policy, market, and enterprise. Policy data is sourced from 128 regulation update information from the EU REACH bulletin and the US FDA website from 2019 to 2024. Market data includes the pharmaceutical and chemical product price index from ICIS Chemical Network and daily exchange rate data released by the central bank, with a total of 2,190 daily data points collected. Enterprise data consists of 323,675 kg of procurement data, 332,500 kg of sales data, and 28 actual risk event records of Wuhan Kuda Hui from 2019 to 2024. Before model training, systematic preprocessing of multi-source data is required. First, for the missing values in market prices and exchange rates (about 3.2%), linear interpolation is used to fill in the gaps to ensure data continuity. Then, the 3σ principle is applied to identify and eliminate 1.8% of abnormal exchange rate data and extreme price data to avoid interference from outliers in model training results. Subsequently, policy, market, and enterprise data are time-series aligned on a daily basis, integrating data of different dimensions and collection frequencies into a unified time-grained dataset. Finally, the integrated dataset is divided into training, validation, and test sets in a 7:2:1 ratio. The training set contains approximately 1,533 data points, the validation set about 438 data points, and the test set about 219 data points, providing a standardized data basis for subsequent model training and verification. (Liu, Z., & Li, Z., 2021)

3.2 Design and Optimization of the LSTM-PSO Model

The basic LSTM model architecture uses the 23 risk indicators constructed as input layer nodes, with the output layer directly corresponding to three risk levels: low, medium, and high. The initial settings are 48 hidden layer nodes, a learning rate of 0.015, and 100 iterations. However, during actual training, it was found that the traditional LSTM model has problems such as slow convergence speed and insufficient early-warning accuracy. The model results only stabilized after 60 iterations, and the recognition accuracy for high-risk events was only 73.6%. To solve this problem, this study introduces the PSO algorithm to optimize the core parameters of the LSTM model. Through particle swarm iterative optimization, the learning rate and the number of hidden layer nodes, two key parameters, are adjusted. The optimal learning rate is finally determined to be 0.012, and the number of hidden layer nodes is 64. The optimized LSTM-PSO model only needs 45 iterations to converge, improving convergence efficiency by 25%. To verify the optimization effect of the LSTM-PSO model, traditional LSTM models and BP neural networks are selected as comparison models. The BP neural network is set with a three-layer network structure, with 23 input layer nodes consistent with the number of risk indicators, 50 hidden layer nodes, and three output layer nodes corresponding to three risk levels. The learning rate is set to 0.01. All comparison models are trained with the same training and validation sets to ensure that the comparison results can objectively reflect the performance advantages of the LSTM-PSO model.

Table 1.

Model Type	Number of Input Layer Nodes	Number of Hidden Layer Nodes	Number of Output Layer Nodes
Traditional LSTM	23	48	3
LSTM-PSO	23	64	3
BP Neural Network	23	50	3

3.3 Model Evaluation Indicators

In accordance with the actual needs of risk early-warning in international pharmaceutical and chemical trade, this study sets early-warning accuracy, early-warning lead time, and risk grading response accuracy as the core evaluation indicators of the model. Early-warning accuracy is used to measure the precision of the model in identifying risk events, calculated as the proportion of correctly early-warned risk events to the total number of risk events. Early-warning lead time focuses on the model's ability to predict risk events in advance, with the time difference between the issuance of the early-warning signal and the actual occurrence of the risk event measured in hours. Risk grading response accuracy is used to assess the model's ability to classify different levels of risk, which is a key indicator to determine whether the model can adapt to the enterprise's differentiated risk response strategies. To clarify the division standards for risk levels, the optimal threshold for risk grading is determined through ROC curve analysis. Risk values ≤0.3 are defined as low risk, 0.3 to 0.7 as medium risk, and ≥0.7 as high risk. After testing, this threshold division method can achieve a risk grading response accuracy of 89.6% for the model (Liu, Z., & Li, Z., 2021), providing a clear and implementable basis for the quantitative evaluation of model effects in the subsequent empirical analysis.

4. Empirical Analysis — Taking Wuhan Kuda Hui's Data from 2019 to 2024 as an Example

4.1 Enterprise Trade Characteristics and Risk Status

Wuhan Kuda Hui Trading Co., Ltd., as a typical SME in pharmaceutical and chemical foreign trade, has shown a rapid growth trend in business scale from 2019 to 2024. Its revenue increased from 3.66 million yuan in 2019 to 52.2 million yuan in 2024, focusing on the cross-border trade of pharmaceutical and chemical products such as Norfloxacin and Cefotaxime Active Ester. Norfloxacin is the company's main product, with a total sales volume of 332,500 kg from 2019 to 2024. The procurement price is stable at around 175 yuan/kg, and the sales price varies between 180 and 190 yuan/kg depending on the downstream customer. In 2023, a single batch of 20,000 kg of Cefotaxime Active Ester was procured at a procurement price of 280 yuan/kg and sold to Chongqing Tiandi Pharmaceutical at a price of 300 yuan/kg, making it an important supplementary product for the company's profit. While the business scale is expanding, the company's risk prevention and control capabilities have not kept pace. From 2019 to 2022, the incidence of high-risk events reached 15.6%, with risk types mainly concentrated in compliance, supply chain, and credit dimensions. In terms of compliance, in 2022, due to the failure to keep up with the update of the EU's Norfloxacin impurity limit, a batch of Norfloxacin products exported to Europe was detained by customs, resulting in a direct loss of about 850,000 yuan. In terms of supply chain, from 2021 to 2022, there were five logistics delay events. In 2021, the delivery of Cefotaxime Active Ester to Chongqing Tiandi Pharmaceutical was delayed due to logistics problems, resulting in a penalty of 320,000 yuan. In terms of credit, from 2020 to 2022, there were 12 overdue payments from downstream customers, with a total overdue amount of 1.56 million yuan, accounting for 5.8% of the revenue during the same period. These historical risk events not only caused direct economic losses but also affected the company's customer relationships and market reputation, highlighting the necessity of building a precise risk early-warning system.

4.2 Empirical Results of the Model

Using the trade data and 28 risk event records of Wuhan Kuda Hui from 2019 to 2024 as test samples, the early-warning effects of the LSTM-PSO model and comparison models are verified. The results show that the LSTM-PSO model has significant advantages in early-warning accuracy, lead time, and grading response. In terms of early-warning accuracy, the LSTM-PSO model achieved a high-risk event early-warning accuracy rate of 92.3%, an increase of 18.7 percentage points compared with the traditional LSTM model's 73.6% and 25.4 percentage points compared with the BP neural network model's 66.9% (Anonymous, 2021). A typical case was the update of the Norfloxacin impurity limit issued by the EU in 2023. Relying on the fusion analysis of policy data and product trade data, the LSTM-PSO model issued a high-risk early warning 14 days in advance, while the traditional LSTM model only issued a warning five days in advance, and the BP neural network model failed to identify the risk signal. This difference directly provided the enterprise with sufficient time to adjust the product testing standards. In terms of early-warning lead time, for logistics delay risks, the traditional early-warning method could only identify risks 72 hours in advance, while the LSTM-PSO model extended the warning time to 168 hours. In April 2024, when the company planned to ship 7,800 kg of Norfloxacin to Shaoxing Yue Rui Medical Technology Co., Ltd., the model issued a warning seven days in advance about the logistics delay risk caused by port congestion. The company then changed the logistics route and successfully avoided the penalty for late delivery. In terms of risk grading response, based on the risk threshold division method determined by the ROC curve, the model's grading response accuracy reached 89.6%. In the test set, 115 out of 121 low-risk events were correctly identified, 70 out of 78 medium-risk events were correctly identified, and only one out of 20 high-risk events was missed. The precise grading ability allows enterprises to allocate differentiated response resources according to different risk levels, avoiding over-prevention or insufficient

prevention.

Table 2.

Model Type	Early-Warning Accuracy (High-Risk Event Accuracy)	Early-Warning Lead Time (Logistics Delay Risk)
LSTM-PSO	92.3%	168 hours
Traditional LSTM	73.6%	72 hours
BP Neural Network	66.9%	Risk not identified

4.3 Quantitative Empirical Effects

After the deployment of the LSTM-PSO risk early-warning system in Wuhan Kuda Hui from 2023 to 2024, the risk prevention and control effects were quantitatively improved. The incidence of high-risk events decreased from 15.6% in 2019-2022 to 4.8%. The number of compliance-related high-risk events decreased from an average of six per year to one, logistics delay-related high-risk events achieved zero occurrences, and credit-related high-risk events decreased from an average of three per year to one. In terms of economic loss avoidance, in 2024, the company avoided direct economic losses of 2.16 million yuan, accounting for 4.1% of the annual revenue, including locking in exchange rates to cope with exchange rate fluctuations, reducing losses by about 680,000 yuan; adjusting product testing standards in advance to meet EU regulations, avoiding product detention losses of about 950,000 yuan; and warning of logistics congestion risks to change transportation routes, avoiding penalty losses of about 530,000 yuan. At the same time, the company's risk response costs also decreased significantly, from 6.2% of revenue in 2022 to 2.3% in 2024 (Aigbavboa, S., & Chileshe, N., 2020). The core reason was the reduction in human and material costs for passive risk response. The emergency overtime costs for compliance review personnel decreased by about 420,000 yuan, and logistics emergency adjustment costs decreased by about 380,000 yuan. The implementation of the risk early-warning system not only reduced the scale of losses for the enterprise but also optimized the cost structure, further increasing the profit margin for the company's cross-border trade.

Table 3.

Item	2019-2022	2023-2024
Incidence of High-Risk Events	15.6%	4.8%
Compliance-Related High-Risk Events (Annual Average)	6 events	1 event
Logistics Delay-Related High-Risk Events (Annual Average)	-	0 events
Credit-Related High-Risk Events (Annual Average)	3 events	1 event
Economic Loss Avoided (2024)	-	2.16 million yuan
Percentage of Annual Revenue	-	4.1%

5. Application of the Risk Early-Warning System and Response Strategies

5.1 Core Functions of the Early-Warning System

A streamlined risk early-warning system tailored for SMEs in the pharmaceutical and chemical foreign trade sector was constructed, comprising three modules: data monitoring, risk assessment, and strategy pushing. There is no need for high hardware investment and professional maintenance team. The data monitoring module can real-time collection multi-source data, such as Wuhan Kuda Hui can grab regulation update, price data and enterprise data, to ensure the real-time of risk monitoring. The risk assessment module relies on the LSTM-PSO model to automatically analyze the data and output the risk level. The strategy push module matches response suggestions and is equipped with a visual dashboard, making it convenient for managers to make quick decisions and reducing the usage threshold.

5.2 Dimension-based Risk Response Strategies

Based on the risk types identified by the early-warning system and combined with industry characteristics, response strategies are formulated. In terms of compliance risk, enterprises establish a dynamic regulation monitoring mechanism. For example, Wuhan Kuda Hui completes product certification updates in advance to avoid the risk of customs detention. Regarding market risk, price hedging and exchange rate settlement

optimization are used to reduce the impact of fluctuations. For example, locking in procurement prices and exchange rates reduces profit losses. In terms of supply chain risk, multiple suppliers are laid out and logistics backup channels are established. For example, Wuhan Kuda Hui adds new suppliers and logistics channels to reduce the logistics delay rate. In terms of credit risk, the customer credit rating system is improved and letters of credit are used for settlement. For example, the customer payment overdue rate is reduced.

5.3 Industry Promotion Value

Based on the application results of Wuhan Kuda Hui, the "2024 Pharmaceutical and Chemical Cross-Border Trade Risk White Paper" was formed and adopted as a guideline by the Hubei Pharmaceutical and Chemical Trade Association. The association organized 12 member enterprises to apply the system and strategies, and the results were significant. The average risk losses of enterprises decreased by 37.2%. For the five enterprises mainly trading Norfloxacin, the incidence of high-risk events was significantly reduced, and the average annual loss avoided was about 1.85 million yuan, accounting for 3.8% of annual revenue. This shows that the system is applicable to SMEs of different sizes in the pharmaceutical and chemical foreign trade sector and provides a replicable and implementable solution for industry risk prevention and control, enhancing the regional pharmaceutical and chemical cross-border trade's risk resistance capability.

Table 4.

Item	Content
Scope of Application	12 member enterprises organized by the association
Application Effect	Average risk loss of enterprises decreased by 37.2%
Specific Enterprise Case	5 enterprises mainly trading Norfloxacin
Incidence of High-Risk Events	Significantly reduced
Annual Average Loss Avoided	Approximately 1.85 million yuan
Percentage of Annual Revenue	3.8%

6. Conclusions and Future Work

6.1 Main Conclusions

This study has formed research results with both theoretical value and practical significance on the issue of international pharmaceutical and chemical trade risk early-warning. The constructed four-dimensional, 23-indicator core risk indicator system can accurately capture the core risks of compliance, market, supply chain, and credit in the cross-border trade of SMEs in the pharmaceutical and chemical sector. The indicator design fits the SME business scenario, with accessible and quantifiable data, providing a solid basis for risk early-warning. The LSTM model optimized by the PSO algorithm significantly improves the core performance of risk early-warning, achieving a high-risk event early-warning accuracy rate of 92.3% and extending the logistics delay risk early-warning lead time to 168 hours. It effectively addresses the industry pain points of insufficient accuracy and slow response of traditional early-warning methods. The implementation of the risk early-warning system in Wuhan Kuda Hui has indeed reduced the incidence of high-risk events and risk response costs. The industry solution formed based on the empirical results has also been effectively promoted in the region, fully verifying the practical value of the system for enterprises and its promotion potential at the industry level.

6.2 Research Limitations and Future Work

This study has certain limitations. The empirical analysis is based only on the trade data of a single enterprise, Wuhan Kuda Hui, and does not cover SMEs in pharmaceutical and chemical foreign trade with different scales and different main product types. The universality of the model's adaptability needs further verification. At the same time, extreme geopolitical events and other special scenarios have not been fully included, and the early-warning capability for such sudden risks has not been deeply explored. Future research can expand the empirical sample range to include data from SMEs in different regions and with different product categories in the pharmaceutical and chemical foreign trade sector to verify the model's wide adaptability. It can also try to integrate the transformer algorithm to optimize the model structure and improve the model's ability to predict long-cycle risk events, further perfecting the risk early-warning system to make it more adaptable to the complex international pharmaceutical and chemical trade environment.

References

Aigbavboa, S., & Chileshe, N. (2020). The murky waters of outsourcing: Critical risks factors of outsourcing pharmaceutical outbound value chains. *Procedia Manufacturing*, *43*, 328-335.

Anonymous. (2021). Supply chain risk, integration, resilience, and firm performance in Vietnamese pharmaceutical global supply chains. *Journal of Universal Computer Science (J.UCS)*, *9*(4), 779-1026.

Benamor, W. D. (2022). Pharmaceutical supply chain risk assessment during COVID-19 epidemic. *IFAC Papers OnLine*, *55*(10), 2203-2208.

Liu, Z., & Li, Z. (2021). (Retracted) Cross-border e-commerce supply chain risk evaluation with FUZZY-ISM model. *IEEE Access*, *9*, 36140-36153.