



The Construction of Market Credit Supervision System for Pharmaceutical Enterprises in Liaoning Province

Luan Lijie, Tian Lijuan*

(School of Business Administration, Shenyang Pharmaceutical University, Shenyang 110016, China)

Abstract

Objective To study the construction of market credit supervision systems for pharmaceutical enterprises in Liaoning Province and to provide suggestions for improving the integrity awareness and production activities. **Methods** Based on the market credit supervision experience of National Medical Products Administration and some other provinces, the construction of supervision laws and regulations system for pharmaceutical enterprises in Liaoning Province was investigated from the perspectives of daily supervision and inspection, joint punishment of illegal acts, sampling results, information communication and publicity. **Results and Conclusion** In recent years, Liaoning Provincial Party Committee and the People's Government of Liaoning Province has attached great importance to the construction of social credit system by issuing a series of local regulations and local government rules. However, the laws and regulations on the market credit supervision of pharmaceutical enterprises are not perfect, and there is a lack of legal documents such as the credit rating method. Besides, some regulatory documents are slightly outdated and they should be revised in time according to the development of the pharmaceutical industry. The Food and Drug Administration of Liaoning Province should promulgate some relevant laws and regulations on the market credit supervision of pharmaceutical enterprises as soon as possible. Firstly, Liaoning Drug Administration should formulate the "Measures for the Administration of Drug Safety Credit of Pharmaceutical Enterprises", including the establishment of credit information management system, which can clarify the main responsibility of pharmaceutical enterprises and key personnel, and standardize drug advertising and advertising endorsement. Secondly, Liaoning Drug Administration should introduce the "Credit Rating Methods for Pharmaceutical Enterprises", and divide the credit rating of pharmaceutical enterprises into four grades from high to low. Besides, differentiated credit supervision measures must be implemented. Finally, the Pharmaceutical Industry Association of Liaoning Province should issue the industry norms that regard drug quality as life so as to improve the integrity awareness of pharmaceutical enterprises and promote the production activities.

Keywords: Liaoning Province; drug safety; pharmaceutical enterprise; credit regulatory system

Pharmaceutical production directly determines the quality and safety of drugs. In recent years,

China's drug incidents have occurred frequently, such as the incident of Ginkgo biloba extract from Guilin Xingda Pharmaceutical, the incident of Changchun Changsheng vaccines and other fake and inferior drugs, which have aroused widespread concern in the public. These drug incidents caused by the dishonesty

* Corresponding author: Tian Lijuan, associate professor. Major research area: Pharmaceutical regulations and policies, rational drug use, history of drug regulation, etc. Tel: 024-23986549, E-mail: tianlijuan_8@126.com.



of pharmaceutical enterprises reflect the lack of market credit supervision [1].

In recent years, China’s government has realized the importance of the construction of market credit system for drug safety. The new version of the “Drug Administration Law of the People’s Republic of China” clearly states that the establishment of drug safety credit files will increase the frequency of supervision and inspection for enterprises with bad credit records, and joint punishment can be implemented according to national regulations [2].

As early as 2005, Liaoning Province began to pay attention to the construction of market credit system. But for the market credit supervision of pharmaceutical enterprises, it only in 2010 issued a “Notice on Issuing the Work Plan of Liaoning Food and Drug Administration to Carry Out the Construction of Drug Safety Credit System” [3]. In addition, the market credit supervision of pharmaceutical enterprises was mentioned in the symposium on “strengthening the normalization of law popularization and promoting the implementation of corporate main responsibility” organized by Liaoning Drug Administration in 2021[4]. However, there are still many deficiencies in the market credit supervision of pharmaceutical enterprises. For example, the regulatory authorities do not have enough credit supervision over production enterprises. Some enterprises still have and illegal production and operation due to their weak awareness of integrity.

To strengthen the laws and regulations system for market credit supervision of pharmaceutical enterprises in Liaoning Province and improve the supervision efficiency, this paper analyzes the

shortcomings of the laws and regulations system for market credit supervision of pharmaceutical enterprises in Liaoning Province by comparing the laws and regulations system of National Medical Products Administration and other provinces, and put forward some suggestions for improving the integrity awareness of pharmaceutical enterprises to ensure the quality of drugs and the safety of public medication.

1 National laws and regulations on market credit supervision of pharmaceutical enterprises

The national drug supervision and administration department pays more attention to the construction of drug safety credit system. As early as 2004, the former State Food and Drug Administration (SFDA) issued “Interim Provisions on Drug Safety Credit Classification Management” [5], which clearly stated that the main responsibilities of drug safety credit rating classification management include the establishment of credit information files of pharmaceutical enterprises and drug R&D institutions according to law. Besides, the division of enterprise credit rating should rely on credit rating standards, and the corresponding rewards and punishments should depend on quality credit rating. Since 2012, China has successively issued “Notice on the Issuance of Drug Safety ‘Blacklist’ Management Regulations (Trial)” [6], “Guiding Opinions on Promoting the Construction of Food and Drug Safety Credit System” [7], “Drug Administration Law of the People’s Republic of China” [2] and other documents. From the initial normative documents to the legal provisions, the legal effect has been continuously improved. The details are shown in Table 1.

Table 1 Related regulatory documents for market credit supervision of pharmaceutical enterprises

Release time	Regulatory document	Main content
August 27, 2019	Drug Administration Law of the People’s Republic of China	The drug supervision and administration department should establish drug safety credit files for drug production enterprises, increase the frequency of supervision and inspection for those with bad credit records, and implement joint punishment in accordance with national regulations; pharmaceutical industry associations should strengthen industry self-discipline, establish and improve industry norms, promote the construction of industry credit system, guide and urge members to carry out activities such as drug production and operation according to law

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Continued Table 1

Release time	Regulatory document	Main content
September 22, 2016	Notice of the Memorandum of Cooperation on Joint Punishment of Serious Dishonest in Food and Drug Production and Operation	The joint punishment targets are drug, cosmetics and medical device manufacturers and operators who have serious dishonest behaviors announced by the food and drug supervision and management department. According to the severity of the serious dishonesty, the corresponding punishment measures are taken
November 19, 2015	Guiding Opinions on Promoting the Construction of Food and Drug Safety Credit System	Accelerate the construction of food and drug safety credit information database and information exchange and sharing platform, carry out credit rating evaluation of food and drug production and operation enterprises and related personnel, realize credit incentive and dishonesty punishment, and ensure food and drug safety to the greatest extent
August 15, 2012	Notice on the Issuance of Drug Safety 'Blacklist' Management Regulations (Trial)	Strengthen the safety supervision and management of drugs and medical devices, establish a record system for illegal acts of production operators, record and publish all illegal acts, improve the entry and exit mechanism of the industry, and urge and warn production operators to fully fulfill their quality and safety responsibilities
September 13, 2004	Notice of the Interim Provisions on Drug Safety Credit Classification Management	The classification management of drug safety credit includes the establishment of credit information files of pharmaceutical and medical device production and operation enterprises and research and development units, the division of credit rating according to credit rating standards, and the corresponding rewards and punishments according to credit rating

2 Comparison of market credit regulatory documents of pharmaceutical enterprises in different provinces

In recent years, under the guidance of national government agencies, local governments and relevant regulatory authorities have generally realized the importance of implementing market credit supervision and formulating corresponding laws and regulations for drug enterprises. Shanghai, Zhejiang, Shaanxi and Tianjin have actively promoted the market credit supervision of drug enterprises, achieving certain results. Their experience is worth learning.

2.1 Market credit supervision documents for pharmaceutical enterprises in Shanghai

The Shanghai Municipal People's Congress and

the People's Government issued local regulations and local government rules on market credit, such as the "Shanghai Social Credit Regulations" ^[8] and "Management Measures of Shanghai Public Credit Information Collection and Use" ^[9]. The basic rules for the collection and use of public credit in Shanghai were formulated which clearly defined specific incentives and disciplinary measures. Since 2014, Shanghai Drug Administration has issued a number of regulatory documents on the market credit supervision of pharmaceutical enterprises. The regulatory content includes both drug safety information and the integrity information of drug production operators. It shows that Shanghai attaches great importance to market credit supervision for drugs. The introduction of such regulatory documents can better regulate and guide the production activities of pharmaceutical enterprises. The details are shown in Table 2.



Table 2 Related regulatory documents for market credit supervision in Shanghai

Release time	Regulatory document	Main content
July 31, 2020	Opinions on Accelerating the Construction of Social Credit System and Building a New Regulatory Mechanism Based on Credit	Improve the pre-credit commitment system, build a credit classification supervision model, improve the post-credit reward and punishment mechanism, strengthen organizational leadership, formulate industry credit behavior, dishonesty behavior standards and incentive and punishment measures, and promote the construction of social credit system
June 23, 2017	Shanghai Social Credit Regulations	It defines the connotation of social credit, establishes the basic rules for the collection and use of public credit, elaborates on the protection of the rights and interests of information subjects, and establishes the basic system of trustworthy incentive and dishonesty punishment
July 8, 2016	Management Measures for Key Supervision Lists of Serious Illegal Food and Drug Production Operators and Related Responsible Personnel in Shanghai	The relevant information of the production operators and their responsible personnel who are subject to administrative or criminal penalties and the relevant restrictions and key monitoring measures taken will be published on the government website
December 30, 2015	Management Measures of Shanghai Public Credit Information Collection and Use	The public credit information is divided into three categories: basic information, good information and dishonest information. At the same time, the regulations clearly stipulate specific incentives and disciplinary measures
August 6, 2014	Notice on Promoting the Pilot Work of Credit Evaluation of Aseptic Drug Production Enterprises	To promote the pilot work in all sterile drug production enterprises in the city, the medical committee of the municipal quality association and the third-party credit service agency to carry out the pilot work of credit evaluation of drug production enterprises, so that relevant enterprises can fully understand the importance of strengthening the construction of credit system

2.2 Market credit supervision documents for pharmaceutical enterprises in Zhejiang Province

Since 2015, Zhejiang Drug Administration has issued the “Management Measures for the List of Serious Dishonest in Food and Drug Safety in Zhejiang Province”^[10] and “Measures for the Administration of Drug Safety Credit of Pharmaceutical Manufacturing Enterprises in Zhejiang Province (Trial)”^[11] and other regulatory documents (Table 3). It is proposed to carry out activities such as credit information collection

and credit rating evaluation for drug production enterprises. With drug quality and safety as the center, credit evaluation indicators are set up. The drug safety credit rating of drug production enterprises is divided into five levels: A (excellent), B (good), C (medium), D (relatively poor) and E (poor). According to the relevant principles of trustworthy incentives and dishonesty punishment, the regulatory authorities implement credit classification services and credit supervision for pharmaceutical manufacturers with different drug safety credit levels.

Table 3 Related regulatory documents for market credit supervision in Zhejiang Province

Release time	Regulatory document	Main content
November 11, 2021	Measures for the Administration of Drug Safety Credit of Pharmaceutical Manufacturing Enterprises in Zhejiang Province (Trial)	The credit information collection, credit rating evaluation, evaluation results release and application of drug quality and safety management in drug production enterprises were carried out by the drug supervision and management department

(to be continued)



Continued Table 3

Release time	Regulatory document	Main content
April 20, 2020	Implementation Opinions on Accelerating the Credit ‘531X’ Project to Build A New Credit-Based Regulatory Mechanism	Establish and improve the three systems of public credit index system, credit comprehensive supervision responsibility system, public credit evaluation and credit joint reward and punishment system, build an integrated public credit information platform across the province, and deepen the innovative application of credit system in several key areas
April 7, 2017	Notice of Implementation Plan of Drug Safety Credit System Construction in Zhejiang Province	By establishing and perfecting the credit system of drug research, production, circulation, centralized procurement, use and other drug safety links, we strive to achieve drug safety traceability, drug quality control and drug safety responsibility
December 22, 2016	Management Measures for the List of Serious Dishonest in Food and Drug Safety in Zhejiang Province	The procedures for the identification, publication, revocation and division of responsibilities of the “serious dishonest list” of food and drug safety were clarified
December 11, 2015	Management Measures for Food and Drug Safety Information Release	Information collection, release, responsibility management and other content, promote the construction of food and drug safety credit system in Zhejiang Province, strengthen the provincial food and drug safety information release management

2.3 Market credit supervision documents for pharmaceutical enterprises in Shanxi Province

Since 2008, the People’s Government of Shaanxi Province has issued local regulations such as “Implementation Opinions on Accelerating the Construction of the Social Credit System in the Province”^[12] and “Measures for the Supervision and Administration of Enterprise Credit in Shaanxi Province”^[13], proposing to establish the social credit system and strengthen the mechanism of trustworthy incentives and dishonesty punishment. According to the credit rating system of pharmaceutical enterprises and the “Measures for Information Sharing and

Joint Punishment of the ‘Blacklist’ of Food and Drug Safety in Shaanxi Province (Trial)”^[14], Shanxi Drug Administration incorporated the administrative penalty information of illegal and dishonest behaviors into the comprehensive evaluation of enterprise credit rating, which timely pushed the credit rating results and “blacklist” related information to the national enterprise credit information publicity platform for the implementation of joint disciplinary measures by the regulatory authorities. These measures can deter criminals, promote the in-depth development of credit supervision and improve the quality and safety of drugs. The details are shown in Table 4.

Table 4 Related regulatory documents for market credit supervision in Shanxi Province

Release time	Regulatory document	Main content
May 5, 2022	Notice on Issuing the Key Points of Drug Safety Credit Supervision in 2022	Expand the scope of credit supervision, strengthen the collection of credit information, realize the docking of enterprise credit risk classification information data, improve the use of credit information and promote the implementation of the joint punishment mechanism for dishonesty
November 18, 2020	The Information Sharing and Joint Disciplinary Measures (Trial) of the Blacklist Information Sharing and Joint Disciplinary Measures (Trial) of Drug Safety in Shaanxi Province	The subject of drug dishonesty with serious illegal dishonesty should be included in the blacklist, and key supervision should be carried out. Public exposure should be carried out according to law, and effective measures should be taken to implement joint punishment for the subject of drug dishonesty included in the blacklist

(to be continued)



Continued Table 4

Release time	Regulatory document	Main content
May 6, 2019	Notice on Further Strengthening the Construction of Drug Safety Credit System	Strengthen the construction of drug credit platform, the collection and application of credit information, and the push of credit information; we will promote joint punishment for dishonesty and joint incentives for trustworthiness, social governance for dishonesty, and interconnection and sharing of credit information
October 15, 2018	Circular on Printing and Issuing the Measures for Administration of Quality Credit Rating and Classification of Pharmaceutical Manufacturing Enterprises in Shaanxi Province	To evaluate and classify the quality credit rating of pharmaceutical production enterprises, and to issue an announcement on the quality credit rating of enterprises
April 18, 2017	Measures for the Supervision and Administration of Enterprise Credit in Shaanxi Province	It is led by the government and participated by the society to collect, share, publicize and apply enterprise credit information, evaluate enterprise credit status, encourage trustworthy enterprises, punish dishonest enterprises and other supervision and management activities, so as to promote enterprises to operate in good faith and improve their credit level
June 26, 2008	Implementation Opinions on Accelerating the Construction of the Social Credit System in the Province	Further establish and improve the social credit system, strengthen the credit incentive and dishonesty punishment mechanism, establish a public credit information sharing platform, actively promote the construction of social credit culture, cultivate the credit awareness of the whole society, and create a good credit environment for honesty and trustworthiness

2.4 Market credit supervision documents for pharmaceutical enterprises in Tianjin

The Standing Committee of Tianjin Municipal People’s Congress has formulated the “Tianjin Social Credit Regulations” [15], including social credit information, trustworthiness incentives and dishonesty punishment, and the construction of social credit environment. Tianjin Drug Administration has formulated the “Interim Measures for Credit Evaluation and Classification Supervision of Pharmaceutical Enterprises in Tianjin” [16]. From March 1, 2021, the credit rating evaluation was implemented in pharmaceutical production

enterprises in the city, with a validity period of 5 years. It stipulated that the credit information of pharmaceutical enterprises included supervision and inspection information, product quality information, and administrative penalty information. The credit information evaluation is collected and evaluated by the drug regulatory office for the administrative inspection, administrative punishment and supervision and inspection of drug enterprises in the administrative region. The credit rating is evaluated by the thousand-point comprehensive scoring method, which is divided into five grades: A, B, C, D and E. The relevant regulatory documents of credit supervision involved in Tianjin are listed in Table 5 below.

Table 5 Related regulatory documents for market credit supervision in Tianjin

Release time	Regulatory document	Main content
January 29, 2021	Interim Measures for Credit Evaluation and Classification Supervision of Pharmaceutical Enterprises in Tianjin	To evaluate the credit rating of enterprises, strengthen the construction of credit system of pharmaceutical production enterprises, promote the implementation of main responsibility of enterprises, guide the honest employment according to law, and promote the healthy development of pharmaceutical production industry

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Continued Table 5

Release time	Regulatory document	Main content
December 6, 2020	Tianjin Social Credit Regulations	The market credit information provider shall collect the information of natural persons with his / her consent and agreed purpose, except as otherwise stipulated by laws and administrative regulations. The debate caused by face recognition has become a realistic problem to be faced
September 11, 2020	Notice of the Municipal Drug Administration on Printing and Issuing the Plan for Promoting the Construction of Integrity Culture and Strengthening the Propaganda of Integrity Theme	Focusing on deepening the reform of decentralization, regulation and service, combining the characteristics of drug supervision, promoting the culture of integrity, establishing the concept of integrity, and improving the integrity awareness and credit level of drug supervision departments and two products and one device market players
March 16, 2018	Notice of Tianjin Market and Quality Supervision and Administration Commission on Issuing the Provisions on the Classification and Repair Procedures for Credit Risk of Market Entities in Tianjin	Strengthen the credit supervision of market entities in Tianjin, strengthen credit constraints, and encourage market entities to operate in good faith

2.5 Market credit supervision documents for pharmaceutical enterprises in Liaoning Province

Since 2005, the people’s government of Liaoning province has issued “Opinions on Strengthening the Construction of Social Credit System”^[17], which clearly put forward the general requirements of establishing social credit system in Liaoning province. Since then, the People’s Congress and the People’s Government of Liaoning Province have successively issued local regulations and local government rules such as “Liaoning Social Credit Regulations”^[18], “Notice on Printing and Issuing the Plan for the Construction of Social Credit System in Liaoning

Province during the 14th Five-Year Plan”^[19], which shows that Liaoning Province attaches great importance to the construction of social credit system. In 2010, Liaoning Province first mentioned the market credit supervision of drug production enterprises, issuing the “Notice on issuing the work plan of Liaoning Food and Drug Administration to carry out the construction of drug safety credit system”^[3]. It proposed to strengthen the construction of drug safety credit system, complete the credit rating of drug production enterprises, and establish a drug safety credit reward and punishment mechanism. The relevant regulatory documents of market credit supervision in Liaoning are listed in Table 6 below.

Table 6 Related regulatory documents for credit supervision in Liaoning Province

Release time	Regulatory document	Main content
January 3, 2022	Notice on Printing and Issuing the Plan for the Construction of Social Credit System in Liaoning Province during the 14th Five-Year Plan	Actively promote local credit legislation, focus on improving the credit standard system, and achieve a basic sound credit laws and regulations, so that credit information from the collection to the application of all aspects of the law, credit information standards consistent, in order to speed up the province’s social credit system to provide legal protection
November 26, 2021	Liaoning Social Credit Regulations	Establish a joint conference mechanism for social credit construction, organize and formulate social credit management systems and standards, implement joint incentives for trustworthiness and joint disciplinary measures for dishonesty, and comprehensively promote social credit construction in the administrative region

(to be continued)



Continued Table 6

May 27, 2021	Liaoning Province Punishment of Serious Breach of Trust Provisions	Punish serious dishonesty, speed up the construction of legal environment and credit environment, and create a social atmosphere of honesty and trustworthiness
December 24, 2019	Decision of the People's Government of Liaoning Province on Strengthening the Construction of Honest Government	Establish and strengthen the system of honest government construction, improve the mechanism of punishment and accountability for dishonesty, and improve the level of honest administration of governments at all levels
December 9, 2016	Notice of the People's Government of Liaoning Province on Printing and Issuing the Implementation Plan for Accelerating the Construction of Social Integrity by Establishing and Perfecting the Joint Incentive and Disciplinary System in Liaoning Province	We should improve the mechanism of praising and encouraging good faith behavior, improve the mechanism of restraining and punishing dishonest behavior, build a cooperative mechanism of joint incentive and joint disciplinary punishment for dishonesty, strengthen the construction of laws and regulations and integrity culture, and strengthen the organization, implementation and supervision and inspection to strengthen the construction of integrity system
April 29, 2010	Notice on issuing the work plan of Liaoning Food and Drug Administration to Carry Out the Construction of Drug Safety Credit System	Carry out the construction of drug safety credit system, build a drug safety credit information platform in Liaoning Province, complete the credit rating of drug production and operation enterprises in Liaoning Province, and establish a drug safety credit reward and punishment mechanism to further strengthen the integrity awareness of drug production and operation enterprises
November 26, 2009	Liaoning Province to Comprehensively Promote the Credit Construction Work Plan	With the support of promoting credit culture and the guarantee of laws and regulations and punishment for dishonesty, the credit information basic platform and service platform of credit system are constructed, and the three credit systems of government, enterprise and individual are established
August 22, 2005	Opinions on Strengthening the Construction of Social Credit System	The general requirements of the construction of the social credit system in the province were clarified. At the same time, the provincial government approved the establishment of a leading group for the construction of the social credit system in the province consisting of 50 departments

3 The situation and problems of the construction of market credit supervision of pharmaceutical enterprises in Liaoning Province

In recent years, the Liaoning Provincial Party Committee and the provincial government have attached great importance to the construction of the social credit system, issuing a series of local regulations and local government rules, such as "Liaoning Province Punishment of Serious Breach of Trust Provisions"^[20] and "Decision of the People's Government of Liaoning Province on strengthening the construction of honest government"^[21]. Among them, "Liaoning Province Punishment of Serious Breach of Trust Provisions" is the first local regulation in China. The introduction of these regulatory documents has further improved the local market

credit system in Liaoning Province and provided a policy support for the development of credit supervision.

Compared with other provinces, the laws and regulations on market credit supervision of pharmaceutical enterprises in Liaoning Province are not perfect because there are no such laws and regulations as credit supervision and credit rating evaluation. Therefore, it cannot provide a strong legal guarantee for regulating the honest production of pharmaceutical enterprises. This will lead to frequent dishonesty of pharmaceutical enterprises and endanger the safety of public medication. In addition, the contents of some regulatory documents on the market credit supervision of pharmaceutical enterprises issued by Liaoning Province are slightly outdated, which cannot meet the needs of the credit



system construction at the present stage. Thirdly, Liaoning Province lacks clear provisions on the main

responsibilities of pharmaceutical manufacturers and key personnel. The details are shown in Table 7.

Table 7 Comparative analysis of relevant regulatory documents of different provincial market credit supervision

Classification	Province				
	Shanghai	Zhejiang	Shanxi	Tianjin	Liaoning
Local regulations	Shanghai Social Credit Regulations		Shanxi Social Credit Regulations	Tianjin Social Credit Regulations	Liaoning Social Credit Regulations
local government rules	Management Measures of Shanghai Public Credit Information Collection and Use		Measures for the Supervision and Administration of Enterprise Credit in Shaanxi Province		Decision of the People's Government of Liaoning Province on strengthening the construction of honest government
Credit rating system		Measures for the Administration of Drug Safety Credit of Pharmaceutical Manufacturing Enterprises in Zhejiang Province (Trial)	Circular on Printing and Issuing the Measures for Administration of Quality Credit Rating and Classification of Pharmaceutical Manufacturing Enterprises in Shaanxi Province	Interim Measures for Credit Evaluation and Classification Supervision of Pharmaceutical Enterprises in Tianjin	
Credit reward and punishment system	Management Measures for Key Supervision Lists of Serious Illegal Food and Drug Production Operators and Related Responsible Personnel in Shanghai	Management Measures for the List of Serious Dishonest in Food and Drug Safety in Zhejiang Province	the Information Sharing and Joint Disciplinary Measures (Trial) of the Blacklist Information Sharing and Joint Disciplinary Measures (Trial) of Drug Safety in Shaanxi Province		Notice of the People's Government of Liaoning Province on Printing and Issuing the Implementation Plan for Accelerating the Construction of Social Integrity by Establishing and Perfecting the Joint Incentive and Disciplinary System in Liaoning Province
Credit information management system	Management Measures of Shanghai Public Credit Information Collection and Use	Measures for the Administration of Drug Safety Credit of Pharmaceutical Manufacturing Enterprises in Zhejiang Province (Trial)	Notice on Issuing the Key Points of Drug Safety Credit Supervision in 2022		



4 Suggestions on establishing the market credit supervision and regulation system of pharmaceutical enterprises in Liaoning Province

4.1 Formulate the “Measures for the Administration of Drug Safety Credit of Pharmaceutical Enterprises in Liaoning Province”

Referring to the “Guiding Opinions on Promoting the Construction of Food and Drug Safety Credit System” issued by CFDA [7] and the “Measures for the Administration of Drug Safety Credit of Pharmaceutical Manufacturing Enterprises in Zhejiang Province (Trial)” [11], the pharmaceutical supervision department of Liaoning Province should formulate the “Measures for the Administration of Drug Safety Credit of Pharmaceutical Enterprises in Liaoning Province” (hereinafter referred to as “Measures”), including the establishment of credit information management system, the clarification of the main responsibilities of pharmaceutical enterprises and key personnel, and the standardization of drug advertising and advertising endorsement.

The credit information management system should be established. Liaoning Drug Administration should pay attention to the construction of credit information system for drug production enterprises. Besides, it should clarify the supervision of credit information, the construction of drug safety credit information database and the disclosure of credit information. It should clearly require pharmaceutical manufacturers to establish credit files and timely record the credit information of drug quality and safety management [22]. According to the credit archives and credit records, through scientific and dynamic evaluation, Liaoning Drug Administration can list the drug production enterprises with better credit on the red list and the ones with poor credit on the blacklist. The red and blacklist with the best and worst credit in the jurisdiction is regularly publicized to the public through publicity columns, newspapers, microblogs and other channels, which enables the public to participate in supervision in time.

The main responsibility of pharmaceutical

enterprises and key personnel should be clarified. As the first responsible person for drug safety, pharmaceutical enterprises should implement the main responsibility system of drug safety and carry out self-examination in the whole process of drug production [23]. We can learn some experience from the “Interim Measures for Credit Evaluation and Classification Supervision of Pharmaceutical Enterprises in Tianjin” issued by the Tianjin Drug Administration. The “Measures” clearly required that pharmaceutical enterprises and key personnel should take their main responsibilities. In addition, the self-examination of enterprises can be used as an important basis for supervision and inspection, which will improve the effectiveness of supervision. The violations of laws and regulations should be punished according to law, which can help to eliminate drug incidents.

Then, drug advertising and advertising endorsements should be standardized. The “Measures” also need to be clarified. Liaoning Drug Administration should cooperate with radio and television and other departments to standardize the examination of drug advertising content, advertising approval, advertising grade filing, advertising management and advertising endorsement. Then, they can severely investigate and punish all kinds False drug advertisement such as exaggerated functions. They should focus on purifying the advertising market and guarding the most important credit line in the pharmaceutical field.

4.2 Issue the “Credit Rating Methods for Pharmaceutical Enterprises in Liaoning Province”

Based on the credit rating management methods issued by Zhejiang Province, Shaanxi Province and Tianjin City, Liaoning Drug Administration should issue the “Credit Rating Methods for Pharmaceutical Enterprises in Liaoning Province” to carry out the credit rating evaluation of pharmaceutical enterprises. According to the “Measures for the Supervision and Administration of Drug Production” and GMP, Liaoning Provincial Food and Drug Administration should carry out supervision and inspection on



enterprises. Based on the results of supervision and inspection and the “Credit Rating Methods for Pharmaceutical Enterprises in Liaoning Province”, the credit rating of pharmaceutical enterprises can be divided into four grades such as A, B, C, and D

from high to low, of which grade A is trustworthy, grade B is basically trustworthy, grade C is dishonest, grade D is seriously dishonest. Then, differentiated credit supervision measures are implemented on these enterprises. The details are shown in Table 8.

Table 8 Supervision measures for credit classification in Liaoning province

Classification	Standard of classification	Credit supervision measure
Trustworthy (grade A)	Within three consecutive years, the enterprise can carry out production activities legally and in compliance, and there is no record of sampling unqualified drugs and administrative penalties	Correspondingly, the number of supervision and inspection should be reduced, mainly based on self-management, but at least once a year. Give credit enterprise integrity advanced model and other honorary titles, while increasing publicity, improve enterprise visibility; on the personal side, personal honors can be enhanced and appropriately supplemented with material rewards
Basically trustworthy (grade B)	In the past two years, no quality accident occurred, and within one year, for violating the regulations and rules of drug management, the regulatory authorities were sentenced to warning administrative penalties, responsibility interviews or ordered to correct within two times	To strengthen targeted supervision and inspection, the number of on-site inspections per year should generally be no less than 2 times, focusing on checking the rectification of existing violations of laws and regulations, and appropriate drug sampling can be carried out
Dishonest (grade C)	Pharmaceutical manufacturers have one of the following situations, assessed as grade C: 1) Quality accidents occurred in the past two years or products were ordered to recall due to quality factors; 2) Within 1 year due to the implementation of the same illegal act by the regulatory authorities to warn, responsibility interview or ordered to correct more than twice; 3) Being warned and ordered to correct the punishment within 1 year for a total of more than 3 times; 4) In the process of supervision and inspection, it is found that there is a large amount of fine or confiscation of illegal property punishment in addition to the warning administrative punishment imposed by the drug supervision and management department for concealing relevant information or providing false materials to the drug supervision and management department, and for violating the regulations and rules of drug management	Strengthen supervision and focus, the annual on-site inspection should generally be no less than 3 times, focus on checking its rectification of existing problems, and increase the frequency of sampling, the legal representative, the person in charge of the implementation of interviews
Seriously dishonest (grade D)	Pharmaceutical production enterprises with one of the following situations, assessed as grade D: 1) Major quality and safety incidents; 2) For violating the regulations and rules of drug management, was ordered to stop production, shut down business rectification, was revoked license, revoked license, product registration certificate, included in the serious illegal drug dishonesty list; 3) The enterprise’s certification certificate of drug production quality management standard has been recovered and revoked according to law; 4) Refusing or obstructing the refusal to cooperate when the supervision department conducts supervision and inspection according to law or asks for relevant information	The implementation of strict supervision, the annual on-site inspection should generally not be less than 4 times, the existing problems within the time limit for rectification, increase the supervision of enterprises, crackdown, punishment and exposure, increase the frequency of its product sampling, increase the intensity of flight inspection, so that the dishonest person a dishonest, everywhere limited

4.3 Industry norms for production and operation issued by the pharmaceutical industry association

The new version of the “Drug Administration Law of the People’s Republic of China” clearly states

that the pharmaceutical industry association should strengthen industry self-discipline, establish and improve industry norms, promote the construction of industry integrity system, and guide members to carry out activities such as drug production and



operation according to law ^[2]. It is suggested that the pharmaceutical industry association of Liaoning Province should issue the industry standard of production and operation according to the latest national regulatory documents. The main contents are as follows.

(1) The awareness of integrity should be cultivated to promote the healthy development of the pharmaceutical industry. Pharmaceutical enterprises should adhere to the integrity of production, paying attention to the construction of enterprise integrity. Besides, they should actively participate in the construction of drug safety credit system. Based on an integrity environment, we can ensure the safety of public medication.

(2) We should adhere to the principle of quality first and people-oriented, so that the public can have safe medicine. We must standardize the production behavior, regard drug quality as the first priority, which can effectively ensure the safety of drug use by the masses.

(3) Pharmaceutical enterprises should improve the consciousness of practicing social responsibility. Pharmaceutical enterprises should actively fulfill social responsibility and assume social obligations. They must protect intellectual property rights, resolutely eliminate false publicity to maintain industry image, and jointly promote the healthy development of the pharmaceutical industry in Liaoning Province.

5 Conclusion

In general, the market credit supervision system of pharmaceutical enterprises in Liaoning Province is not perfect. Therefore, Liaoning Province should establish the market credit supervision system of pharmaceutical enterprises as soon as possible. Firstly, the drug administration department of Liaoning Province should formulate the “Measures for the Administration of Drug Safety Credit of Pharmaceutical Enterprises in Liaoning Province” to record and evaluate the credit information of drug quality and safety management in drug manufacturing enterprises. For example, they can standardize

drug advertising and advertising endorsements, strictly investigate and punish all kinds of drug false advertising, and investigate the responsibility of false advertising enterprises and spokesmen. Secondly, Liaoning Drug Administration should issue the “Credit Rating Methods for Pharmaceutical Enterprises in Liaoning Province”. They should take the quality and safety of drugs as the center, setting up credit evaluation indicators, and strengthening the credit supervision and punishment of pharmaceutical enterprises. Finally, the Pharmaceutical Industry Association of Liaoning Province should issue the industry norms of production and operation, standardize the order of pharmaceutical production, fulfill the responsibilities of better protecting public health and medication.

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