A STUDY ON THE ELECTRONIC SUPERVISION MODEL OF DRUG DISTRIBUTION

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Abstract: Drugs, as a special commodity, is directly related to people's lives and health, so it is essential to effectively supervise the drug distribution process Current electronic supervision of drugs effectively regulates the market order, but it also faces with many problems, such as high cost in the comprehensive promotion and low efficiency of logistics operations. Therefore, this paper summarizes the principle of current electronic supervision and analyzes the existing problems. Based on these and combined with the characteristics of flow conservation in pharmaceutical logistics system, this paper presents a new model of electronic supervision and compares it with the current model, in order to solve the problems in China's current pharmaceutical distribution supervision.

1 INTRODUCTION

Drug is a special kind of goods that's related to the health and the safety of people. In order to safeguard people's health, maintain the society stability and promote the healthy development of China's pharmaceutical industry, it's very important to strengthen the management of drugs, and ensure that people can get safe and effective drug timely. As a channel between the producers and patients, The distribution of drug involves logistics, capital flow, business flow, information flow and other complicated process, and the supervision of it is not only an important part of the supervision work, but also the key to ensure the quality of drug, standardize drug distribution channels, stop the fake drugs' manufacturing and selling, and promote the reformation of drug circulation system.

In order to achieve the goal of supervising and administrating drug distribution, State food and drug administration has established a regulatory mechanism for complaint, random inspection and supervision, but these regulatory mechanisms happen after the distribution, when most of the counterfeit drugs have entered the market and threatened people's safety and health. In addition, with the changes in the function of drug administration and supervision, the supervising and administrating task in the field of food and drug has gradually increased, so the limited supervisors cannot undertake the current heavy task, and it's no longer suit the current work for the supervision of drug distribution that relying on "crowd strategy" and "large area of investigation".

So our country urgently needs a high-efficiency means for drug distribution that can run automatically all the time to standardize drug distribution channels, stop the fake drugs' manufacturing and selling, and ensure that people can get safe drug timely. Electronic supervision is an innovative means that State food and drug administration is implementing.

From the initial narcotic drugs and the first kind of psychotropic substances in 2007 and the "four major categories of key drugs" in 2008 to the 307 kinds of drugs in National Essential Drugs List in 2011, the implementation of the scope of electronic supervision is gradually expanding. According to the statistics, narcotic drugs and first kind of

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psychotropic substances involve of 18 drug manufacturers, and 560 drug wholesalers; the second kind of psychotropic drugs, blood products, vaccines, and Chinese medicine injection, which we call "four major categories of key drugs", involve of 568 drugs manufacturers and 13000 drug wholesalers; the 307 essential drugs involve of 3567 drug manufacturers, accounting for 76% of all manufacturing enterprises. Thus, the drug electronic supervision is pushing on steadily and safely.

2 PRINCIPLE OF CURRENT DRUG ELECTRONIC SUPERVISION

Current drug electronic supervision mainly rely on China's drug electronic supervision network, which is an information net the State food and drug administration adopts to supervise the drugs manufacturing and circulation enterprises. Moreover, it is also a net system based on the Public information service platform which covers all over the country, and the methods and tools by which the State food and drug administration implement for electric supervision. Their working principle can be concluded as “One code throughout, all process supervised”.

2.1 One Code Throughout

By the rules of State food and drug administration, the drugs which are listed on the China’s drug electronic supervision network to implement electric supervision have to be pasted one universal drug electric supervision code, which is called “E-ID”. Otherwise any kinds of drug are not allowed to be put on the shelves of pharmacy agent. The electric supervision code will accompany with the drug during the whole flow process.

2.2 All Process Supervised

The registered drug manufacturers should apply for drug electric supervision code from China's drug electronic supervision network before they produce drugs. Then the code should be adhered to drug’s minimum sale unit. Before the drug’s entrance to the warehouse of manufacturers, these codes will keep the state of being “not activated”, the corresponding drugs cannot be searched on the drug electronic supervision network, and the drug can't circulate.

Initially, the enterprises will scan and upload the information of the code before the single drug with electric supervision code entering the warehouse of drug manufactures. Soon the corresponding drug can be searched on China’s drug electronic supervision network, thus these kinds of drugs come into effect, and then the flow was legal. It is just by the working theory of “write in” and “write out” that those drugs’ process supervision comes into reality. As is showed in figure 1. (Note: Nowadays, China’s drug electronic supervision network has not covered all the nation’s drug agents and consumers.)

Taking pharmaceutical wholesale enterprise as an example, pharmaceutical wholesale enterprise must scan each electronic supervision code and upload the information to China's drug electronic supervision network as soon as it receives the drugs from manufacturers. The system will check the information one by one automatically with the" write off" information from manufacturers, until confirming all medicines arrived are correct. Then pharmaceutical wholesale enterprise records the

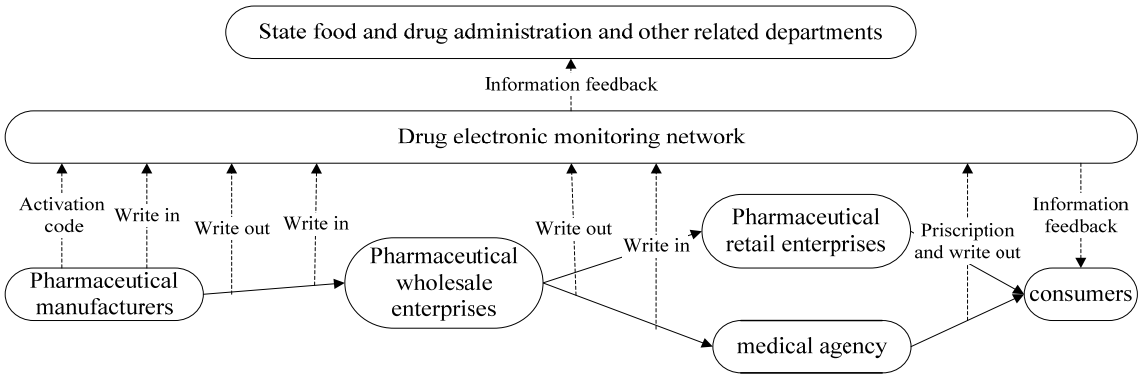

Figure 1: Principle of current drug electronic supervision.

information in their own "account book", and we call this process "write in"; When delivery, the pharmaceutical wholesale enterprises must scan each electronic supervision code, and upload the information The system will check the information one by one automatically with the" account book", until confirming all medicines outbound are correct. Pharmaceutical wholesale enterprise eliminates the drugs from its "account book", and we call this process "write off." If a single product goes wrong, the system will alarm, and "write in" or "write off" will not proceed. Through the "write in" and "write off" process of the entire circulation, the background database system of China's drug electronic supervision network records every single product's major pharmaceutical logistics "path" from the manufacturer to the final sale, so that consumers can inquire the basic information of the drugs he bought, while the food and drug administration departments' real-time supervision of the whole process of drug distribution can be achieved.

3 THE PROBLEMS EXISTING IN CURRENT DRUG ELECTRONIC SUPERVISION MODE

The current model of drug electronic supervision resolves many problems that exist in the traditional supervision, makes the automatic and real-time supervision to the circulation process possible, ensures in stipulated time to complete the recall of problem drugs, improves the extent of comprehensive utilization supervision resources, promotes the drug regulatory departments' work efficiency at all levels , effectively regulates the drug distribution market order, and guarantees people's safe drug use. The current drug electronic supervision mode takes the minimum sale unit as drug regulatory object, which is "an object, a code", and it also records most of the logistics "path" of a single product from drug manufacturers to the final sale of drug companies. However, with the gradual expansion of the supervision scope, current drug electronic supervision will face more and more challenges.

3.1 High Cost of Comprehensive Promotion

In current electronic supervision mode, the cost includes enterprises' annuity of access key, labelling system renovation cost of drug manufacturers' production line, information collection equipments cost of drug circulation, and maintenance cost of electronic supervision network system.

Drug product and business enterprises need to apply for access key to join the electronic supervision network; and the key digital certificate's annual service fee is 300 Yuan per enterprise. Taking 3850000 drug enterprises to calculate, the current drugs electronic supervision annual enterprise access key fee will reach 116 million Yuan. To meet the requirements of electronic supervision drugs, the manufacturers which have accessed to the network must affix electronic supervision code to each single product, which requires transformation of the original production line to increase the labelling system. If each drug manufacturer production line labelling system transformation needs a million Yuan, the full implementation of current electronic supervision mode will at least cost 47 million Yuan. The current drug electronic supervision model for each single product needs the circulation process "write in", "write out" operation, which requires all links in drug circulation use information collection devices to collect and unload information. If each enterprise purchasing information collection device needs to spend 100 Yuan, the full implementation of current electronic supervision mode will at least cost 380 million Yuan.

In addition, considering China's electronic supervision network system's upgrade and maintenance cost, at least millions Yuan per year will need.

3.2 Heavy Load of Information System

The number of annual drug sales is about 150 million. If we adopt current electronic supervision mode to supervise all drugs sold in China, the electronic supervision network system will have to handle at least ten billions of "write in" and "write out" data. Coupled with data from previous years, electronic supervision network data processing system will face a huge challenge. With hundreds of millions information stored in the background system of China's electronic supervision network, it

may lead to the system's slowly run thereby to reduce the supervision efficiency, meanwhile it also increases the risk of system crash or paralyze. Once the system is paralytic, drug product and business enterprises will be unable to carry out normal inbound and outbound work, business operations will be affected, and drug supply will be suffered, which even bring about serious social problems.

3.3 Low Efficiency of Enterprise Logistics

Current drug electronic supervision model requires drug product and business enterprises must collect and unload each single drug's information in order to complete the process of "write in", and "write out". For large scale drug product and business enterprises, the information collection operation will directly affect the efficiency of logistics, and one-dimensional code in the form of drug electronic supervision makes it difficult to achieve mass of information collection, which severely limits the enterprises' operational efficiency.

Overall, current drug electronic supervision mode has a high cost of comprehensive, and the benefits are limited, so the foreground is not optimistic. Therefore, China still needs to explore others effective technological means to supervise the drug distribution, rectify market order, curb the fake drugs' manufacturing and selling, and ensure that people can get safe and effective drug timely.

4 NEW MODEL OF ELECTRONIC SUPERVISION FOR DRUG DISTRIBUTION

In China, each kind of drug on sale has a corresponding drug approval number. A drug approval number corresponds to a production of a pharmaceutical manufacturer. Therefore, if you want to supervise the distribution process of a certain kind of drugs, in theory the supervision of effective drug approval number can be enough.

Drug manufacturers, who obtain a drug approval number, can be drug's legitimate pharmaceutical manufacturers. Meanwhile, in order to supervise the drugs quality of pharmaceutical manufacturers, and trace and review of the marketed drugs production history, we use "batch number" to identify the drugs in the same production cycle. Therefore, drugs with the same approval number and the same batch number can be considered by the same manufacturer who use the same materials in the same production process, and the nature and quality can be considered to be basically the same only installed in the different sub-drug sale unit. In this case, China's drug supervision and management departments can use the same batch number and the approval number of drugs as a whole in supervising drug distribution.

According to the relevant provisions of China's current electronic supervision, for the drug product and business enterprises, once drugs' purchasing or selling occurs, the two parties must scan the electronic supervision code of each single product and upload the electronic supervision code, trading notes and other related information to China's drug electronic supervision network. Therefore, if we implement electronic supervision for all kinds of drugs, all systems' inflow and outflow can be supervised in real time in the pharmaceutical logistics system, including manufacturers, wholesalers, and retailers.

When there are no illegal drugs between the distribution and no problem of logistics activities, for the drugs with the same approval number and batch number, the flow monitored in the pharmaceutical logistics system should be conserved, as shown in Figure 2.

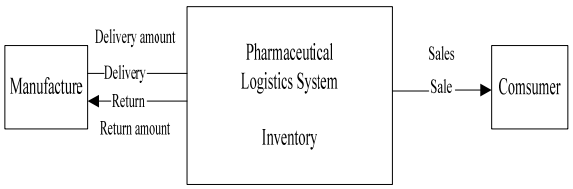

Figure 2: Flow conservation in pharmaceutical logistics systems.

In Figure 2, beginning from the drugs flow into the pharmaceutical logistics system to a certain moment, the cumulative amount of manufacturer sending to the pharmaceutical logistics system should equal the sum of the cumulative amount returning from the logistics system to manufacturer, the cumulative sales to consumers and inventory of drug logistics system of the present moment. It can be expressed by an equation:

Delivery amount=Return amount+Sales+Inventory

For each constituent in the supervision system, the system's cumulative input flow is equal to the cumulative output flow and the current inventory of system. An equation can be showed as follows:

Input flow=Out flow+Inventory

Here, we call the equation "addition sum relationship", and the difference of the "total input flow" minus the "total output flow" and "the current system inventory", which we call "supervision coefficient of pharmaceutical logistics system total network flow", being expressed with γ.

For the drugs with the same approval number and batch number, the initial inventory of each constituent in the supervision system is zero before distribution. When China's drug electronic supervision network receives the information uploaded by the constituents in pharmaceutical logistics system, the system will automatically calculate the "supervision coefficient of pharmaceutical logistics system total network flow" and calculate each constituent's current inventory based on "addition sum relationship", and then the result will be compared with zero. In this way, we can monitor the drug logistics system timely and automatically. The inventory of each constituent should not be less than zero in pharmaceutical logistics system.

(1) When γ equal to zero, there are two cases:

1) If each constituent's current inventory of the monitored system is nonnegative, it means there are no illegal drugs mixed, that's to say, the drugs are in normal circulation.

2) If a constituent's current inventory of the monitored system is negative, it means this constituent (wholesaler or retailer) have a more cumulative outflows than inflows, that is to say this constituent produced and sold illegal of drugs, or this constituent did not report the inflow information, and drugs distribute abnormal in this condition.

(2) When γ is less than zero, it means there are illegal drugs mixed, drugs distribute abnormally. This is because one constituent (wholesaler or retailer) in the network of the pharmaceutical logistics system purchased illegal drugs, then uploaded the inflow information, the supervision system calculates the constituent's current inventory through "addition sum" relationship and finds it increase, so the current inventory of the pharmaceutical logistics system will equal the increase, resulting in cumulative inflows will be less than the sum of cumulative outflows and current inventory, making the "supervision coefficient of pharmaceutical logistics system total network flow" is less than zero.

(3) When γ is greater than zero, it means some drugs have not flowed into the monitored system, or there is a constituent sold drugs to other enterprises out of this system, although both cases belong to illegal operations, but no matter what kind of situation, the drugs flowing are legal drugs, no illegal drugs mixed.

It is necessary to indicate that this new model of electronic supervision for drug distribution is only applicable to the drugs with the same approval number and batch number, if we want to apply this mechanism to monitor all drugs, just using the above mechanism respectively for all the drugs with the same approval number and batch number.

5 THE COMPARISON OF TWO DRUG ELECTRONIC SUPERVISION MODES

The new mode of electronic supervision on drug circulation put forward in this paper is based on China's current drug electronic supervision; it is an innovation of electronic supervision. Compared with China's current drug electronic supervision mode, both similarities and differences exist.

From table 1, we know that the new mode can achieve the same results with China's current electronic supervision, but because of the new mode's regulatory precision expands to the varieties grade (namely the drugs with the same approval number and batch number) from the single grade, it will reduce the regulatory costs greatly.

At the same time, using the new mode, China's drug electronic supervision network just needs to record the flow information in each constituent (manufacturers, wholesalers, retailers) of drugs with the same approval number and batch number, which greatly reduces drug electronic supervision's information processing load, and makes it possible to achieve mass of information collection, thereby enhancing the efficiency of enterprise logistics.

6 CONCLUSIONS

Using the new mode of drug electronic supervision, the problems existing in current drug circulation electronic supervision such as high cost of comprehensive promotion, heavy load system information, and low efficiency of business logistics, all have been solved very well. In order to enhance

Table 1: The comparison of two drug electronic supervision modes.

Items	Current drug electronic supervision mode	New mode of drug electronic supervision
Regulatory scope	The whole country	An administrative areas or the whole country
Control mode	General investigation, beforehand control	General investigation, beforehand control
Regulatory precision	Single drug	The same batch number
Regulatory cost	High	Low
Regulatory efficiency	High	High
Drug identification	Drug electronic supervision code	approval number and batch number
Anomaly judgment	Whether the information of "write in" and "write out" completely match	Whether the flow of drug logistics system is conservative
Drug recall	Support	Support
Process supervision	Realizable	Realizable

the efficiency of State food and drug administration at all levels, standardize the market order of drug circulation, and guarantee people's safe drug use in a better way, our country should carry out the new mode of drug electronic supervision vigorously.

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APPENDIX

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