

The Improvement of Chinese Second Category Vaccines Supervision System from the Perspective of Supervision Elements: Based on a Case Study of the Shandong Problematic Vaccines Incident in China

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Abstract: The vaccination system is divided into two categories in China. The first is mandatory vaccination, mostly free and using domestic vaccines under the National Immunization Program. The second is alternative vaccination, which patents must pay for. In March 2016 Shandong Province in China, a vaccine scandal occurred, which is known as the Shandong problematic vaccines incident. The incident involved 24 provinces and regions in China, The vaccine safety affects hundreds of millions of people. And all the problematic vaccines involved are second category vaccines. It exposed a variety of existing problems for the Chinese second category vaccines supervision system. Based on the analysis perspective of supervision elements, this paper makes a case study by analyzing the five supervision elements, which include: the subject and objects of supervision, supervision institutions, supervision resources and supervision environment. And it focuses on the problems of the Chinese second category vaccines supervision system exposed in the case, including: the administration level and the team scale of supervision subject-as not match with its duty; the interest-oriented awareness of supervision objects being insufficient; the vaccine tracking institution not being complete; the professional supervision of human resources being insufficient; the participation of social supervision being insufficient. Based on these deficiencies, this paper puts forward a series of improvement recommendations, combined with the case analysis and some supervision experience of American cases. It includes prescriptive elements that: strengthen the supervision authority of the supervision subject and enhance the supervision status by law and administrative order; ensure the adequate financial supply of disease control and prevention departments to reduce the regulation violation desire of supervision objects; improve the cold chain logistics management and tracking institutions of the vaccine; strengthen the vaccine supervision professionals to optimize the supervision resources; expand the participation of citizen supervision and media supervision to optimize the supervision environment.

Keywords: vaccines supervision, supervision elements, Chinese second category vaccines, Shandong problematic vaccines incident

INTRODUCTION

Since the foundation of China, it has developed great processes in terms of vaccine management systems. On the aspect of vaccination scale, China has become one of the countries that have the largest vaccination amounts in the world. Hundreds of millions of newborn and other people have been vaccinated. On the aspect of vaccination effect, China has controlled smallpox, polio, hepatitis b and several other diseases successfully by vaccination. For example, according to the estimations of Health and Family Planning Commission of China, from 1992 to 2009, 92 million people were prevented from the infection of hepatitis b through the means of vaccination [1]. The vaccination system is divided into two categories at present in China. The first is mandatory vaccination, mostly free and using domestic vaccines under the National Immunization Program. The second is alternative vaccination, which patents

must pay for. The first category vaccine is centralized purchased in trading platforms at the province level, and then distributed to diseases control departments and vaccination sites. However, the second category vaccine is allowed to be purchased by diseases control departments and vaccination sites, which are also in charge of vaccination. Compared with the first category vaccines, the second category vaccines are charged and have a bigger profit space. Chinese vaccine quality management system passed the National Vaccine Management System Assessment of the World Health Organization in 2011, which means that the Chinese vaccine quality management system is kept in line with international standards. And it also passed the reassessment in 2014. But this does not mean that the Chinese vaccine regulatory system is without any problems. In March 2016 Shandong Province in China, there occurred a vaccine scandal, which is known as the Shandong problematic vaccines incident. The incident

involved in 24 provinces and regions in China. The vaccine safety affects hundreds of millions of people. It reflects that the Chinese vaccine supervision system has many problems. All the problematic vaccines in this accident are second category vaccines. Because of the great range and influence, the news, condemning, this accident was wildly spread via social media. At the same time, this accident fully exposed huge problems existing in the second category vaccine supervision system. This paper makes a case analysis about the Shandong problematic vaccines incident. It presents this accident with time order. Then it takes the second category vaccine supervision system in China as the research object, and analyzes the problems of the second category vaccine supervision system exposed in this accident from five key elements of the supervision system (the subject and objects of supervision, supervision institutions, supervision resources and supervision environment). After that, it puts forward some suggestions to improve the second category vaccine supervision system in China, combining with the situation in China and experience in other developed countries. Therefore, this paper divides into three parts: the first one is the case introduction of Shandong problematic vaccines incident, the second is a case analysis of Shandong problematic vaccines incident and the third comprises suggestions for the second category vaccine supervision system in China.

INTRODUCTION OF THE SHANDONG PROBLEMATIC VACCINES INCIDENT

Shandong problematic vaccines incident originated in the second half of 2014 in Jinan, the capital city of Shandong Province. Police in Jinan found a person named Peng Mouwei involved in an illegal case of selling vaccines. On April 28, 2015, Jinan police successfully sequestered the warehouse of Peng Mouwei and sequestered lots of second category vaccines, which include 25 kinds of second category vaccines and was worth 700 thousand RMB. At the same time, polices caught another criminal. In 22 suspects' control bank accounts, the illegal income in these accounts was as high as 310 million RMB, with the expenditure as high as 260 million RMB, and the aggregate amount of these accounts up to 570 million RMB. After investigation, this incident involved 24 provinces and regions in China, the vaccines affected hundreds of millions of people.

Peng Mouwei, the main criminal in this case, once was sentenced for three years, and five years of probation due to the illegal operation of the vaccine. However, after the judgment, she continued to engage in selling the vaccines without permission and treated the judgment as nothing. In 2013, She came to Jinan. And she pulled her daughter into sell vaccines illegally together a year later. Her daughter was responsible for contacting upstream and downstream, sending and receiving of the vaccines. Under the conditions without

any medicine trade license, Peng Mouwei and her daughter used the online chat tools and published lots of vaccine selling information in many chat groups. They brought in lots of second category vaccines from the drug company salesmen or illegal operations staffs. Then they improved the price and sold these vaccines to the downstream illegal operations staffs or some vaccination basic sites in remote areas. In order to reduce the purchase cost, they bought the vaccines that are near the deadline of shelf life. Some vaccines are found less than two months to the deadline of their shelf life. And because of lacking professional vaccine transportation equipment, they just used the expresses that contained some ice bags to reduce the temperature to delivery the vaccines. It lead to the vaccines escaped from cold chain of 2 to 8 degrees Celsius, and naturally made the quality without guarantee.

On February 2, 2016, the public security bureau of Jinan city handed over this case to procuratorate and reported this case to society.

On March 18, 2016, Bloomberg news interviewed and published a report about this incident. And it made lots of hidden rules and scandals be presented in Chinese public sphere. In this accident, some vaccine makers and wholesalers salt illegally to Peng Mouwei and other people who had no certificate to sell vaccines. Then these vaccines were out of control. At the same time, the wholesalers went through the supervision using fake dates to hide the illegal vaccine sales. After they got vaccines, Peng Mouwei and other people sent these to some disease control departments and vaccination sites at grass-root level and used other low prices and other measures. These reports caused millions of Chinese people to feel hugely angry, especially some parents who had small babies. And this topic became the hot topic of Chinese social medias.

On March 18, 2016, the National Food and Drug Supervision and Administration Bureau publish a notice to ask the food and drug supervision bureau in Shandong province to take effective measures to quickly investigate all the information of this incident and find out all the vaccines involved in this accident.

On March 21, 2016, the food and drug supervision bureau in Shandong province announced, after checking the vaccine varieties list provided by police, there were 12 kinds of vaccines, 2 kinds of immunoglobulin, 1 kind of therapeutic biological products involved in this case. And all the 12 kinds of vaccine are second category vaccines, without the first category vaccines.

On March 22, 2016, Chinese premier Li Keqiang made important instructions for this case.

On April 13, premier Li Keqiang chaired a council about the survey report of Shandong problematic vaccines incident. On this council, it made a decision to

take an accountability program to a group of officers who needed to be responsible for this accident. And it made a decision to amend the regulations about the management of vaccines circulation and vaccinations in China. It put forward that: firstly, all the second category vaccines need to be centralized purchased on a trading platform at the province level. All the wholesalers are not allowed to sell vaccines. Secondly, it will establish a traceability system in the whole process of the vaccine from production to use. All the disease control departments and vaccination sites have a duty to record the vaccine transportation and reserve temperature. And it also added some punishment regulations to illegal actions in the vaccine industry. After this council, the discussion and public attention of this incident gradually died down.

THE CASE ANALYSIS OF SHANDONG PROBLEMATIC VACCINES INCIDENT

For a supervision system, it includes five elements, these respectively are: supervision subject and supervision object, supervision institutions, supervision resources and supervision environment. The five elements influence each other and constitute an organic system of supervision. Among them, the supervision subject is the core power. Supervision object is the object to make actions. Supervision institutions are the action rules. Supervision resources are the realistic foundations of supervision. And the supervision environment is the external condition to supervision. As a kind of administrative power, the generation and strength of supervision ability depends on the integration degree and optimization level of these five elements [2]. In this part, it analyzes the problems that were exposed in the case from the perspective of the above five supervision elements.

Supervision subject

The management and supervision of vaccine products is divided according to the administration level. In particular, for the second category vaccine, the disease control departments in different levels are in charge of purchase and vaccination at different administration levels from nation level to town level. And similarly, the food and drug supervision departments are responsible for the supervision of second category vaccines at different levels. However, in the practice of administration in the Chinese government, the disease control departments enjoy higher administrative authority and are half a level higher than the food and drug supervision departments. This phenomenon directly constrains the performance of supervision duty for the food and drug supervision departments. In addition, the food and drug administration is responsible for the food and drug supervision and administration at the same time, and their duty range is very wide, but managers and team numbers are limited. In the face of the huge supervision work, it is hard to avoid to appearing some supervision leak, which is happened in the case at hand.

Supervision object

There are two types of supervision objects in the Chinese second category vaccine supervision system: vaccine manufactures, are responsible for the production of vaccines; and diseases control departments, vaccination sites and vaccine wholesale, are responsible for purchase and vaccination. For the vaccine manufactures, there are lots of strict supervision institutions. And in this case, the quality of second category vaccines involved in this accident is good and of a high safety standard. In contrast, this case was a reflection of various problems existing in diseases control departments and vaccination sites.

In order to build an effective market of second category vaccine and to decrease the price of second category vaccines through market competition, after 2005, the diseases control departments and vaccination sites are allowed to purchase second category vaccines from vaccine manufactures or vaccine wholesalers in the market by themselves. Since then, the purchasing power of second category vaccine belongs to the diseases control departments and vaccination site at different levels. In reality, when the purchase of second category vaccines becomes a commercial activity, the diseases control departments and vaccination sites aim at purchasing profit instead of improving public services quality. And it is not a single phenomenon that some diseases control departments take it as a mean to create department income and warfare [3]. When some of the qualified wholesale enterprises and disease control departments purchase a large number of vaccines at a low price, how to sell vaccines with a higher price becomes the main aim for them. With a profit motive, they try to control the cost of the transportation or choose the vaccines that are near the end of their shelf life and can be bought at a cheap price. Finally, consumers pay a high price for second category vaccines. Because there are limited choices for them when they get a vaccination, the prices remain high. At the same time, the quality and safety of vaccines is difficult to guarantee. In this case, the illegal vaccine dealers make cooperation with some disease control departments with illegal benefit exchanges to sell large amounts of second category vaccines are sold without guarantees for quality and safety. In sum, these factors are what makes such incidents happen.

Supervision institutions

As mentioned before, China began to implement a classification management system of first category vaccines and second category vaccines in 2005. Compared with the first category supervision system, the second category vaccine supervision system has a broader range and some more complex procedures. But in supervision practice of second category vaccine, the supervision departments tend to focus on the examination and verification of qualification of vaccine manufactures, which is similar to first category vaccine

supervision. And they pay little attention to the transportation and storage. Therefore, as exposed in the case, some illegal vaccines dealers can easily pass the review of qualification by forging accounts and affiliating qualifications.

In addition, after 2008, China established a special system of electronic supervision codes to track the flow of each vaccine better. Every vaccine is assigned an electronic supervision code. Therefore, the production, transportation and vaccination status can be clearly recorded. And it brings great convenience to tracking vaccines, and dealing with untoward effects, as well as for monitoring disease prevalence. But this electronic supervision code system has been suspended because it was complained that it brought unfair competition to the vaccine market. Then, it became difficult to track all the problematic vaccines back in the short time involved in this incident.

Supervision resources

Supervision resources mainly contain the supervision of human resources and financial resources. For the aspect of supervision of human resources, in 2016, there are 5000 medicine or vaccine manufactures and 12,000 wholesale enterprises in China. However, the number of qualified and special inspection staff is about 500. The regulatory inspection cannot avoid having some blind spots as a result of this imbalance in human resources. Despite that, in recent years, coupled with institutional reform, the system has also brought a certain impact into grassroots supervision. And supervision departments staff rotation make the number of professional inspection teams more stretched.

When people get a vaccination, they can reduce the infection sources of some diseases and to prevent other people from becoming infected. Therefore, the vaccine has the nature of public goods. And the second category vaccine also has characteristics of public goods. From this point of view, government has a duty to provide financial support to provide second category vaccines to society and people. But at present, the financial input of public health services for the Chinese government is not enough and the proportion in total GDP is too small [4]. It makes the cold chain system of second category vaccines need to be supported by the market instead of government. Once it becomes a business, if there is no strict and effect supervision measures, it is unavoidable that some illegal action to reduce cost and add profit will occur. And this is the essence of the Shandong problematic vaccines incident.

Supervision environment

The supervision environment means the external factors which can directly or indirectly influence the activities and results of supervision subjects. In this case, it mainly reflects some disadvantages of the media supervision environment in China. From this case, it reflects that the quality and speed of the media supervision environment in China is much weaker than

in developed countries. Take America as an example, the media supervision environment provides great help to the vaccine supervision system in America. It is very common that media reports some scandals or news and then provides important information to supervision departments. However, most medias in China lack the spirit to find and expose illegal actions in society or the medicine industry independently. For example, in this incident, before the medias started to reports this incident, polices had uncovered and announced this case. The large amount of media reports didn't provide any important information to the supervision system in China. On the contract, some media even used some unclear words to report this incident. It creates some panic to the society and brings a great crisis of confidence to vaccine supervision departments.

SUGGESTIONS FOR THE CHINESE SECOND CATEGORY VACCINE SUPERVISION SYSTEM

As mentioned in the case introduction, after this accident, the Chinese government has already made some changes and improvements to complete the second category vaccine supervision system. It has great expectations to bring lots of benefits for the vaccines management in China. Based on the above, some other aspect also should make some improvements.

Strengthen the administrative authority of food and drug supervision departments to improve the administrative status of supervision subjects

Currently, the food and drug supervision departments, the second category vaccine supervision subject, have a lower administrative level than the disease control departments, the supervision object. It restricts the supervision effect in practice, especially in China, a country in which the administrative level has a great effect on administrative practice. Therefore, it is necessary to establish the absolute authority of food and drug supervision departments on second category vaccine supervision from the perspectives of both legislation and administrative practice. On the one hand, it needs to make a statement in administrative law to make clear that diseases control departments have a duty to receive the supervision from food and drug supervision departments. On the other hand, it should establish a strong accountability system. If some diseases control departments or officers can't fulfill their second category vaccine supervision requests or have committed negative acts, they need to receive a full accountability procedure.

Provide adequate financial support to diseases control departments and vaccination sites to reduce the regulation violation willingness of supervision objects

The neglect of public functions is one of most important problems in Chinese disease control departments. And one of the key reasons is that the

government has insufficient total financial input and has an inefficient input system [5]. Therefore, it is necessary to allocate a reasonable budget for diseases control departments and vaccination sites, especially those at the grassroots level, to ensure adequate financial support for them. It can then eliminate the phenomenon that diseases control departments and vaccination sites take second category vaccines as department income resources. Then it can reduce the regulation violation willingness of supervision objects and the pressure of supervision departments.

Rebuild the electronic supervision code to improve the vaccine trace institution

A good vaccine supervision system must have a complete and efficient trace system. Once there appear some problematic vaccines, it can trace the production, distribution and use scale rapidly. The pause of electronic vaccine supervision codes has brought a huge loophole into the supervision system, and it is the main reason that the problematic vaccines cannot be traced quickly. The Chinese government should consider rebuilding the electronic vaccine supervision code. The specific approach can refer to the practice of the American vaccine supervision system. During the practice of the American vaccine supervision system, software vendors, hardware vendors, cloud providers, and pharmaceutical companies are completely separate. Data is not required to be stored in the American Food and Drug Administration or a monopoly of a specified database. Each process has the service competition of dozens of providers. And the market can make the price of trace services become low enough to stand. And it also avoids a data monopoly.

Strengthen the professional vaccine supervision staff team built to optimize the supervision of human resources

The professional vaccine supervision staff team is one of the key determinants of the supervision system. The American Food and Drug Administration is famous for its the strict supervision and great supervision effects. It builds a vaccine supervision staff team that has several professional groups. They keep close attention to the each adverse event that is reported. If there are some vaccines which are found to be unsafe, it will immediately order the vaccine manufacturers to recall or withdrawal. Even the slightest violation will bring great cost, so this encourages the vaccine to be made to be safe and is effective in the protection of such via incentivizing it adherence. At present, the scale of professional vaccine supervision staff teams does not match with the vaccines market scale. Therefore, it must be a special focus on the cultivation of the professional vaccine supervision staff team built to optimize the supervision of human resources. Then it will improve the responsiveness and handling capacity of the second category vaccine supervision system.

Expand the social participation of second category vaccine supervision to optimize the supervision environment.

The public is the vaccination beneficiary and stakeholder of vaccine quality. In the context of increasingly stressing the “social participation in governance” concept, the social participation in second category vaccine supervision is not sufficient [6]. At present, there are two main kinds of social participation in China: public participation and media participation. As the main user of vaccines, the public has direct contact with the operation and management of vaccination sites. It has a large quantity of opportunities to find an illegitimate phenomenon. Therefore, the second category vaccine supervision department can create some convenient report channels, such as a report website and public platforms in Wechat and Weibo. The vaccine supervision department can receive abundant and important information if the report channel is convenient enough. It will bring great benefit to vaccine supervision practices. At the same time, the vaccine supervision departments should strengthen the information cooperation with the mass media. Through the establishment of an effective information-sharing mechanism, the gathering of vaccine supervision information and the public opinion guidance can be realized. Then it can help to create a favorable media environment for vaccine supervision, and promote the upgrading of the quality of the vaccine supervision system.

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