Disclosure of Vaccine Risk and Emergency Legislation in China

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ABSTRACT

China is the world’s largest vaccine producer and consumer, mainly using domestic vaccines. However, many of the vaccines produced domestically have experienced quality problems, and in addition, an illegal vaccine industry has been growing. The Chinese government has amended its laws twice in more than a decade in an effort to address these issues and plans to enact a specific vaccine administration law. This law will strictly regulate the production, circulation, and administration of vaccines, as well as control domestic vaccine manufacturers and medical institutions. Foreign vaccine manufacturers intending to enter the Chinese market will face both opportunities and difficulties as a result of the new regulatory regime.

Public health research has shown that vaccination can significantly reduce the incidence of infectious diseases. But a vaccine needs a long-time, large-scale adoption for efficacy. Along the chain of production, storage, transportation, and vaccination, there are some environmental and technical risks; also, vaccines are mainly administered to minors and patients. These issues have required China’s government to take measures to ensure vaccine quality and reduce adverse reactions.1 In addition, China had started an immunization program against severe infectious diseases in 1978. Through hard work, the death and disability rates of smallpox and polio were reduced to almost zero in China. At the same time, China’s vaccine industry was growing rapidly, with vaccine production and the quality of some vaccines leading the world.2 However, China found loopholes in its vaccine safety in recent years, exposing a regional public safety crisis that has affected millions of people. As a result, China has been taking urgent legislative measures to ensure its population’s health and restore public health credibility.

I. REFLECTION ON CURRENT VACCINE REGULATIONS IN CHINA

China’s currently effective law on vaccine is the Regulations of Vaccine Circulation and Inoculation.3 The Regulations were formulated by the State Council in 2005 and have a total of 76 articles. The contents include general principles, vaccine circulation, vaccination, safeguards, treatment of adverse reactions, supervision and administration, and legal liability. But the Regulations are less effective than the Drug Administration Law and the Infectious Diseases Prevention Law and is limited in scope: it only regulates vaccines already on the market. Significant matters involving vaccines are regulated by other laws. Legal issues involving vaccine research, clinical trials, and listing licenses have to also comply with

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2J. Hendriks, Y. Liang, B. Zeng, China’s Emerging Vaccine Industry, 6(7) HUMAN VACCINES 602–607 (2010).
3This file is available in Chinese at http://samr.cfda.gov.cn/WS01/CL1030/151243.html
A. Vaccine classification

The Regulations divide vaccines into first-class and second-class vaccines. First-class vaccines are vaccines required for Chinese residents, especially children, such as the smallpox vaccine and poliomyelitis vaccine. In addition, a small number of emergency or group vaccinations against infectious diseases, such as SARS vaccines, are also considered first-class vaccines. Second-class vaccines are voluntary vaccines, including the influenza vaccine, duovirus vaccine, and so on. First-class vaccines are free, while the cost of second-class vaccines is borne by the recipient.

The government is most concerned about first-class vaccines’ production and vaccination. The Regulations required the Ministry of Health (MOH) to develop a national immunization program to screen first-class vaccines based on epidemic trends and financial conditions. So far, the MOH has announced that in order to prevent 15 infectious diseases (including hepatitis B, tuberculosis, poliomyelitis, pertussis, diphtheria, tetanus, measles, hepatitis A, epidemic meningitis, epidemic encephalitis, rubella, mumps, hemorrhagic fever, anthrax, and leptospirosis), the government will provide first-class vaccines to Chinese residents free of charge.

B. Procurement and transportation of vaccines

Because of the dual management system of “medical care” and “drugs” adopted by China, the MOH is responsible for vaccination administration and the China Food and Drug Administration (CFDA) is responsible for the production quality and circulation of vaccines.

To ensure the rate of vaccination and its safety, the Regulations stipulate that first-class vaccines produced by pharmaceutical companies should adopt government procurement channels and be sold only to the Centers for Disease Control and Prevention (CDC), not to pharmacies and hospitals. Second-class vaccines are centrally purchased by the CDC and resupplied to other medical institutions. For the storage and transportation of vaccines, the Regulations provide for cold chain transportation with temperature control labels if necessary. All kinds of files, such as vaccine certificates, customs forms for imported vaccines, vaccine sales records, storage records, distribution records, supply records, and temperature records, shall be kept for inspection until two years after the expiry date of the vaccine.

C. Vaccination

With regard to the vaccination program, the Regulations require health departments of each province to develop immunization procedures and guidelines for the use of vaccines, which involve epidemiological investigations, advocacy, training, technical guidance, monitoring, evaluation, emergency management, etc. Because of China’s large population, in addition to the CDC and public hospitals, private hospitals, private clinics, rural health centers, trained rural doctors, certified medical assistants, and nurses have been permitted to administer inoculations. The Regulations require those administering vaccinations to be equipped with qualified refrigerated facilities and a vaccine custody system.

The Regulations distinguish general vaccination and special vaccination. During general vaccination, in order to prevent the leakage of the vaccination, the Regulations stipulate that infants shall be provided a vaccination certificate after birth and shall receive free vaccine at their domicile or in their regular residence. Residents may also choose to receive imported vaccines which are the same as the first-class vaccines (however, the cost of imported vaccines is paid by the residents themselves). Inoculation with a second-class vaccine is voluntary. Before inoculation, medical personnel shall record the identification information, source, and the expiry date of the vaccine. After inoculation, medical personnel shall record the inoculation time and the name of the person administering the vaccine. These records must be recorded in the immunization record card.
preserved for five years. Medical personnel should also know the inoculated person’s health status and determine whether any adverse reactions occur.\(^{12}\)

In regards to special vaccinations, the Regulations stipulate that in order to control the outbreak and prevalence of infectious diseases, the health department may propose to carry out mass vaccinations in affected areas and may take emergency vaccination measures. Health departments can publish recommendations for second-class vaccines, but vaccine producers and hospitals cannot advertise to patients to encourage them to get vaccinated.\(^{13}\)

There are several steps specified for investigating adverse vaccination reactions after inoculation. The first step is exercising judgment. Based on the functional indicators of the inoculated person’s tissue and organs, medical personnel should determine whether any adverse reactions were caused by vaccines. The Regulations stipulate, however, that the general response and the neogenetic reaction of an inoculated person are not adverse reactions. The second step is to report and investigate: medical personnel should report adverse reactions to the health department and drug supervision departments. Individual adverse reactions will be investigated by CDC and confirmed by CFDA, while major adverse reactions will be investigated by MOH and CFDA. The third step is appraisal: when an individual inoculated person dies or is severely disabled, or many inoculated people incur adverse reactions, an evaluation is made as to whether there has been medical malpractice.\(^{14}\) The fourth step is providing compensation for adverse vaccine reactions, inoculation errors, or the use of unqualified vaccines. According to the result of the appraisal, compensation for harm done by first-class vaccines (free vaccines) is provided by the government, while for second-class vaccines, it is provided by the vaccine manufacturers.

D. Supervisory power

According to the Regulations, the whole process of vaccine production, storage, transportation, and use must be carefully tracked. Vaccines that cannot be traced back shall be destroyed by MOH and CFDA.\(^{15}\) The Regulations stipulate that the drug supervisory department may carry out random checks on the storage, transportation, supply, sale, distribution, and use of vaccines, and that it possesses the power to seal up and seize vaccines or production materials. The health department can inspect the purchasing, distributing, refrigerating, and inoculating process of vaccines in medical institutions, and may take emergency measures, such as sealing up vaccines that are found to be fake or of dubious quality.\(^{16}\) The Regulations stipulate that the health department and the drug supervisory department should cooperate to monitor vaccine quality and inform each other of adverse vaccine reactions. Chinese residents can also expose and report vaccine problems.

E. Legal liability

The Regulations propose that health officials whose negligence contributed to adverse reactions or other significant problems with vaccines should resign or otherwise leave their positions. One possible situation where resignation would be appropriate: if the responsible official(s) of the health department and/or the drug supervisory department failed in supervision, failed to detect the illegal act in time, failed to manage the lower agencies, or failed to handle the adverse reaction incident and/or carried out wrong group vaccination, the official(s) should resign.\(^{17}\) A second situation: if an official delayed vaccination resulting in the spread of infectious diseases, an epidemic, or other serious public health consequences, the official(s) should resign.\(^{18}\) A third situation: if there was a serious vaccine safety or quality incident in a jurisdiction, the senior officers of the health department and the drug supervisory department should resign.

According to the Regulations, official and medical personnel who did not abide by safety regulations during a vaccine’s distribution, cold chain management, the acceptance of vaccines, or vaccine record keeping would be subject to administrative sanctions.

To sanction vaccine manufacturers, the Regulations mainly has adopted fines. The specific standards are: (1) if the vaccine packaging was unqualified, a fine of 5,000 yuan to 20,000 yuan should be imposed; (2) if the vaccine was part of an illegal transaction, a fine of 2–5 times the trading volume should be imposed; (3) if the vaccine was not stored and transported in a cold chain, a fine of 2–5 times of the

\(\text{\(^{12}\)}\)\text{Regulations of Vaccine Circulation and Inoculation, Article 25.}\n\(\text{\(^{13}\)}\text{Regulations of Vaccine Circulation and Inoculation, Articles 31, 33.}\n\(\text{\(^{14}\)}\text{Regulations of Vaccine Circulation and Inoculation, Articles 40, 41.}\n\(\text{\(^{15}\)}\text{Regulations of Vaccine Circulation and Inoculation, Article 55.}\n\(\text{\(^{16}\)}\text{Regulations of Vaccine Circulation and Inoculation, Articles 48, 50.}\n\(\text{\(^{17}\)}\text{Regulations of Vaccine Circulation and Inoculation, Article 56.}\n\(\text{\(^{18}\)}\text{Regulations of Vaccine Circulation and Inoculation, Article 57.}\)
II. CHAIN CRISIS IN VACCINE PRODUCTION, CIRCULATION, AND VACCINATION IN CHINA

Since the implementation of the Regulations in 2005, there have been more than 10 vaccine incidents in various provinces of China, some of which have reached criminal levels.

A. The quality of vaccine production was out of control

In 2008, Hebei Fuer Biopharmaceutical Co., Ltd. and Jiangsu Yanshen Biotechnology Co., Ltd. produced seven batches of rabies vaccine, a total of 215,800 doses. A year later, CFDA looked into vaccine quality problems. In 2009, Liaoning Dalian Jingang Andy Biological Products Co., Ltd. reported that a rabies vaccine for humans produced by the company had added nucleic acid substances, that the curative effect was only 49% of that of the regular vaccine, and that it could not prevent rabies in the incubation period.

A larger quality-related incident involved Changchun Changsheng Biotechnology Co., Ltd. This is a listed company which is the leading vaccine producer in China. In 2017, CFDA conducted a spot-check and found that the active ingredient index of the “adsorbed acellular DPT combined Vaccine” did not meet the good manufacturing practice (GMP) standard. A total of 499,800 doses of the vaccine were sold to Shandong and Anhui provinces, and most of the unqualified vaccines had been used. After investigation, CFDA identified the vaccine as being a substandard drug. The penalty was to confiscate 186 doses of stocking vaccine, confiscate illegal income (850,000 yuan), impose a fine of three times the produced value (2.58 million yuan), and cancel the drug’s GMP certificate. At the same time, the government arranged for children who had been vaccinated with the problematic vaccine to be vaccinated again.

In 2018, the company was found to have fabricated and falsified records about the production of its rabies vaccines. The investigation found that since April 2014, some vaccines had been mixed with expired vaccines; some vaccines had no manufacture date and batch number; and some vaccines had been produced on fake dates. Some of these vaccines were sold in China and some were exported abroad. CFDA revoked all kinds of approval certificates of the company, confiscated illegally produced vaccines, confiscated illegal income (1.89 billion yuan), and imposed a fine of three times the sales value (7.21 billion yuan). The chairman of the company and 14 executives were forbidden for life from engaging in the pharmaceutical industry. The judiciary charged them with producing fake drugs. At the same time, CFDA recalled the vaccines, collected data about adverse reactions, and compensated the vaccinated patients. This was the biggest vaccine safety incident in China. In its wake, the Director of CFDA, Bi Jinquan, resigned, two vice-governors of Jilin province have been removed from office, and more than 30 government officials have been held accountable for their actions.

In 2017, the CFDA found that 400,000 DPT vaccines produced by Wuhan Institute of Biological Products Co., Ltd. did not meet the GMP standard. The vaccines were sold to Hebei Province, Chongqing, China, and most residents therein had been vaccinated with problematic vaccines. The most likely cause of the vaccine failure was the production process. Additionally, in 2016, 30,000 doses of the DPT vaccines produced by Yuxi Watson Biotechnology Co., Ltd. were investigated for failing to reach the required drug potency. This indicates that China’s largest producers of DPT vaccines all have been found to have created substandard vaccines.

B. Illegal sale, transportation of vaccines

In 2012, Shandong police received a report that a drugstore was privately buying and selling vaccines. After investigation, it was found that the drugstore bought and sold vaccines for up to seven years; had been selling more than 40,000 doses of influenza, hepatitis B, rabies, and varicella vaccines; and that the aggregate price of the vaccines was 120 million yuan. The vaccines, which were purchased from various vaccine companies, were simply cooled with ice and then sold to hospitals and clinics with a profit of 20–30 yuan per dose. The main recipients of these vaccines are adults, though they were also administered to some children.

In 2016, Shandong Province cracked a larger case of illegal vaccine sales, mainly of second-class vaccines, including freeze-dried rabies vaccine (Vero cells), inactivated polio vaccine, haemophilus influenzae B combined vaccine, live attenuated B encephalitis vaccine, mumps attenuated live vaccine,
D. Falsification of vaccines

C. Illegal vaccination

sentenced to 19 years in prison. The perpetrators purchased vaccines from 13 vaccine manufacturers. Most of these vaccines were close to the expiration of the quality guarantee period, after which they can no longer be sold, only destroyed. As a result, vaccine manufacturers were willing to sell them at low prices to the perpetrators, who in turn sold these vaccines to 25 provinces. Storage and transportation issues exacerbated the quality/safety risk, especially in some of the remote areas in which they were sold, as there were no cold chain logistics. The perpetrators made a profit of 50 million yuan. The criminal organization had a huge sales network, with more than 400 salesmen and 45 drug-trading enterprises helping the perpetrators create false drug sales records and leasing or loaning drug-trading licenses. What makes people angry is that some of the buyers of these vaccines were regulators and drug-trading enterprises helping the perpetrators create false drug sales records and leasing or loaning drug-trading licenses. What makes people angry is that some of the buyers of these vaccines were regular health clinics. After the investigation, 190 people were indicted and the principal offender was sentenced to 19 years in prison.

C. Illegal vaccination

On June 16, 2005, village doctors in Sixian County, Anhui Province, inoculated 2,500 students with hepatitis A vaccine. Subsequently, 216 cases of adverse reactions occurred and a six-year-old student died. The cause of the incident was that the vaccines were purchased through unknown channels and it was a preventive vaccination campaign which had not been reported to the government.

D. Falsification of vaccines

A five-year-old boy was vaccinated with a rabies vaccine after being bitten by a dog in Laibin, Guangxi, China, in 2009, but died 21 days later. After testing, the vaccine was found to be a fake. This was not an isolated incident: medical institutions buy more than 10,000 vaccines from the black market.

These cases have hit China’s vaccine production, sales, and regulatory system, and also have caused distrust among residents. Residents of wealthy regions choose to go to Hong Kong and foreign countries to get vaccinated, while some of China’s top private clinics secretly import vaccines from abroad to meet the needs of their clients.

III. EMERGENCY LEGISLATION OF THE CHINESE GOVERNMENT

Most of the vaccine supply models designed by the Chinese government are nonprofit oriented and are licensed by the CDC. But vaccines and medicines are similar in that there is a large market demand as well as a large difference between the factory price and the actual sales price. Criminals obtain vaccines in a variety of ways and sell them for profit. Vaccine manufacturers can make money by selling vaccines to the CDC or to the black market. CFDA has found that the illegal chain of vaccine sales and transportation has been difficult to eradicate.

As a kind of drug, vaccines should strictly follow the manufacturing quality standard. There are more than 30 specialized vaccine manufacturing enterprises in China. Although the number is not large, the number of vaccines produced each year reaches 700 million people. The quality management level of the vaccine production enterprise is uneven. Some batches of vaccines are of poor quality and some companies are negligently or even deliberately failing to comply with the Regulations. At present, there are only a few hundred drug quality inspectors in China, who are accordingly unable to carry out a reasonable proportion of spot-checks.

In order to ensure the biological activity of vaccines, most vaccines cannot be preserved at room temperature, and the environmental temperature conditions for transportation and storage are very strict. However, at present, the vaccine storage and transportation system in China is not sufficiently developed—especially for vaccines transported to border areas. Some vaccines need to be packed and split before inoculation; improper storage methods reduce the vaccine’s potency and increase the probability of adverse reactions.

In the vaccine case involving Changsheng Biological Company in 2017, CFDA was held accountable by the State Council and unanimously condemned by the media. In order to reverse the adverse situation, CFDA urgently completed the draft of the Vaccine Administration Law in just four months. In December 2018, the State Council brought the draft for consideration by the Standing Committee of the National People’s Congress of China. There were some new changes in the draft.

19This file is available at http://www.npc.gov.cn/npc/flcazqyj/2019-01/04/content_2070153.htm
A. Legal effect

The current Regulations of the Vaccine Circulation and Inoculation are only administrative regulations promulgated by the State Council. In the future, the Vaccine Administration Law will establish comprehensive regulation of vaccine research and development, clinical trials, marketing authority, quality standards, vaccine purchasing, storage, transportation, inoculation, adverse reaction, compensation, and so on. Vaccines will be regulated independently from other drugs; the Vaccine Administration Law and Drug Administration Law will be equally effective. China’s leaders have also proposed “the most stringent standards, the strictest supervision, the most severe punishment, the most serious accountability” for the management of vaccines. This means that the Vaccine Administration Law will be more stringent than the Drug Administration Law.

B. Content aspect

The Vaccine Administration Law (Draft) consists of 10 chapters and 88 articles. Changes have been made in a number of areas as compared to the Regulations of Vaccine Circulation and Inoculation:

1. Reclassify vaccines. The draft divides vaccines into two categories: immunization program vaccines and non-immunization program vaccines. Immunization program vaccines can be further divided into national immunization program vaccines and other immunization program vaccines. National immunization program vaccines are determined by the MOH and CFDA and should be compulsory inoculation. Other immunization programs vaccines are decided by each province. Immunization program vaccines are free, while there is a charge for non-immunization program vaccines. Procurement authority for all vaccines is concentrated in provincial drug administration agencies.

2. A drug marking authority certificate must be obtained for vaccine marketing. The vaccine development process is consistent with that for other drugs, requiring clinical trials and ethical reviews. Vaccine applicants should provide true, adequate, and reliable research data, materials, and samples. The draft provides for a conditional advance listing system, where conditional approval may be granted if the benefit of the vaccine is determined to outweigh the risk. The draft also provides for the elimination of vaccines that are designed or manufactured in an unsafe way or which are ineffective.20

3. Establish a system of vaccines license holders. An organization that only obtains the vaccine marking authority certificate cannot produce the vaccine. Rather, it must meet the special production conditions in order to be able to become a vaccine license holder. The requirements to become a vaccine license holder are stricter than those for general drug production enterprises. At the same time, officers employed by vaccine license holders must pass the CFDA qualification examination, have a professional background in pharmacology, have rich experience in the field, and have a good personal credit record. In addition, the vaccine license holders must produce vaccines on their own and cannot entrust other enterprises to help produce the vaccines. Vaccine license holders must be responsible for the whole process, from research through production, to distribution and to inoculation. Vaccines license holders are also responsible to provide compulsory insurance for vaccines and for accident compensation.

4. Administration. The draft stipulates that the examination, approval, and production of vaccines; flight inspection; and post-marketing evaluation are under the authority of the CFDA, while the procurement and use of vaccines shall be the responsibility of the MOH. The vaccines must be delivered by the vaccine license holders themselves: sent first to the CDC, and then to the vaccinating hospital. Other agencies are not allowed to participate. CFDA has two more powers than in the past: one is to send inspectors to vaccine license holders,21 and the second is to recall a suspicious vaccine.

5. Vaccine production. The draft requires that the whole process of vaccine production be recorded, that test data should be checked, and that the whole process can be traced back.22 Vaccine license holders must accurately record process deviations, quality differences, failures, and accidents during production. Vaccine makers should carry out a batch licensing system, and each batch of products must be approved by the CFDA-authorized agency.23 The retention time for all production records has been increased from two years to five years.

6. Report reward system. The draft establishes a reporting system for vaccine production enterprises, and awards substantial prizes to enterprise insiders who are successful in reporting.

7. Legal liability. The Drug Administration Law stipulates that when counterfeit drugs are produced

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20Vaccine Administration Law (Draft), Article 32.
21Vaccine Administration Law (Draft), Article 59.
22Vaccine Administration Law (Draft), Article 22.
23Vaccine Administration Law (Draft), Articles 23, 24, 25.
or sold, the counterfeit drugs and the illegally obtained income therefrom will be confiscated and a fine of not less than two to five times the value of the drugs may be imposed. If it is an inferior drug, it is also subject to a fine of one to three times the value of the drug. The draft has raised the minimum amount of the fine, clearly stipulating that if the vaccine produced or sold is a fake vaccine, not only will the illegal production and illegally obtained income be confiscated, but concurrently, a fine of not less than five to ten times the value of the vaccines shall be imposed. If the value is less than 50,000 yuan, the fine imposed shall be 250,000 yuan to 500,000 yuan. If the circumstances are serious, the vaccine license shall be revoked, and a fine of not less than 15–30 times the value of the vaccines shall be imposed.

If the vaccine produced and sold is an inferior vaccine, the minimum penalty limit will be raised from the current “one to three times” to “two to five times.” If the value of the vaccine is less than 50,000 yuan, a fine ranging from 100,000 yuan to 300,000 yuan shall be imposed. If the circumstances are serious, a fine of 10–15 times the value of the vaccine may be imposed.

The draft also stipulates that if an officer of a vaccine license holder commits a violation, the license holder shall pay the forfeit from salary, a fine will be imposed, and the license holder will not be allowed to engage in vaccine production or trading activities for 10 years or more. Consumers who are physically damaged by the vaccine may claim punitive damages.

IV. OUTLOOK

According to optimistic estimates, China’s Vaccine Administration Law, the world’s only law specifically designed for vaccines, will be enacted in 2019. This will have several positive impacts on China’s vaccine industry.

First, the law should help improve the quality of vaccine development. In the past, vaccine development in China received assistance from Japan and the World Health Organization (WHO). Now, however, the Chinese government has come to recognize that only high levels of domestic research can guarantee the quality of vaccine mass production. After the enactment of the law, the Chinese government will support both basic and applied research on vaccines and formulate plans for the development of the vaccine industry.

Second, the law helps reverse the vaccine crisis. China is the world’s largest vaccine producer, producing more than one billion doses a year, and Chinese companies are pushing vaccine exports aggressively. In 2011 and 2014, China passed the WHO national vaccine regulatory system evaluation. Some domestic vaccines have also been pre-certified by WHO programs and purchased by the United Nations Children’s Fund (UNICEF) and the Global Alliance for Vaccine and Immunization (GAVI), but successive crises have seriously affected the reputation of Chinese vaccines. The government wants to pass the strict laws to crack down the manufacture of inferior vaccines.

Third, despite the above improvements, the draft needs to be further improved. At present, China has not included therapeutic vaccines, such as cervical cancer vaccines, in its Vaccine Administration Law. The draft does not definitively determine whether people who want to be vaccinated have the option to buy imported vaccines, or even to get vaccinated in foreign hospitals, as a growing number of wealthy people want.

Fourth, vaccine supervision will encounter a series of challenges, and there will still be a variety of vaccine safety incidents. At present, the focus of supervision is on vaccine producers. For the negligence of regulatory officials and the medical malpractice of medical personnel, the penalties prescribed by the draft should be lighter. But residents complain a great deal about official non- and malfeasance; this concern has been addressed by heavy penalties. However, too-heavy penalties can result in paralysis by officials whose focus is on avoiding sanctions; that is why a better balance in terms of penalties needs to be struck. Notwithstanding issues about the severity of sanctions, it is important to continue to increase the monitoring of vaccine regulation and supervision.

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24 Vaccine Administration Law (Draft), Articles 70, 71, 73.
25 Vaccine Administration Law (Draft), Article 83.