The Historical Evolution of China’s Drug Regulatory System

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Executive Summary

China’s drug regulatory system has experienced a complicated path of evolution. China had no independent drug regulatory system during the period of its “command economy”. The quality and safety of pharmaceutical products was assured by governmental control of every aspect of the pharmaceutical industry. After reforms were introduced in 1978, both the government regulators and the regulated pharmaceutical industry faced a number of challenges related to the effective control of the quality and safety of pharmaceutical products. This challenge has been addressed recently by a transition to an independent drug regulatory system. The history shows how challenging it is to turn the drug regulatory system and pharmaceutical industry from one that is controlled centrally to one that is based on private-sector companies. The introduction of an independent regulatory system has improved the regulator’s ability to supervise the quality and safety of drugs. However, many impediments still exist both inside and outside China’s drug regulatory system that appear to be best served by a gradual rather than radical reform.
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1. Introduction

The pharmaceutical industry has produced many drugs that have benefited people by improving their health. Nevertheless, pharmaceutical industry interests can sometimes diverge from, or even conflict with, public health. It is therefore necessary to establish a system to regulate the pharmaceutical industry that can assess effectively whether drug products are sufficiently safe and efficacious to be permitted on the market\(^1\).

China’s population is anticipated to peak at 1.4 billion in 2025\(^2\), and the country’s demographic transition is being accompanied by rapid economic growth and an increased consumption of drug products. The vast size of China’s drug consumption has made China’s drug regulatory issues of major interest to international researchers.

China’s drug regulatory system has experienced a complicated period of evolution. During the period of command economy, China had no independent drug regulatory system. The regulators and the regulated were interdependent. The regulated pharmaceutical industry depended on the drug administrative department to direct their planning and decision-making. The drug administrative department of the government, as the regulator, depended for its financial support on the success of the industry. After China began to reform the command economy system, the overriding goal of the drug administrative department as well as the government became the promotion of industrial development. China’s drug administrative department began to promote the development of the pharmaceutical industry as an engine of economic growth, and was then confronted with new challenges to control the quality and safety of drugs. In order to improve the methods by which oversight was administered, China tried to establish an independent drug regulatory system. Because systems associated with the previous governmental approaches are difficult to change, China has experienced a growth curve with work still to do.
The characteristics of an independent regulatory system include three key elements\(^3\): First, the regulatory system should have a purpose that confines itself to initiatives that can correct market failure, maintain effective competition and reduce social risks and public health problems. Second, the regulatory intervention in economic activities should be indirect to avoid impeding the commercial activities of the market participants. Third, regulatory agencies should be relatively independent with respect to the interests of industry. The role of the regulatory agencies should be that of referees instead of athletes.

According to the above standards China has never had a fully independent regulatory system but is now moving in this direction. This article discusses the historical evolution and dilemma of China’s drug regulatory system by examining the historical and structural factors that affect the results of this process. It further provides some reflections on policy implications associated with the reform of the present system.
2 China’s drug regulatory system before the reform policy (1949~1977)

2.1 The role of China’s competent departments for pharmaceutical industry

China’s competent departments responsible for the domestic pharmaceutical industry were a series of regulatory bodies in the government. They took charge of planning and other important decision-making for state-owned pharmaceutical enterprises.

In 1956 there were about 500 privately-owned pharmaceutical factories, more than 300 privately-owned factories of medical devices, more than 7000 privately-owned pharmacies, and more than 100,000 merchants of Chinese traditional herbal medicine. The development of the Campaign of State-Private Joint Ownership eventually turned most privately-owned enterprises into state-owned enterprises. Similarly, most privately-owned hospitals and clinics were also transferred from private sector to direct government control.

In order to operate all of its state-owned enterprises a series of competent departments were set up to manage the pharmaceutical industry. The new Pharmaceutical Company of China was assigned to take charge of the nation’s wholesale trade of pharmaceuticals in 1950. The Agency of Pharmaceutical Industry was assigned to take charge of the manufacturing business of chemical medicine and medical devices in 1952. The Traditional Herbal Medicine Company of China was assigned to take charge of the wholesale trade of traditional herbal medicine in 1955. All of these competent departments were responsible for high-level management of the state-owned enterprises no matter what their names and no matter the ministries to which they was assigned. They took charge of business arrangements and administrative affairs as well as drug quality control.
2.2 The role of China’s drug supervising agencies

After 1949, the government eventually took almost all privately-owned pharmaceutical enterprises under direct governmental control. In order to operate and regulate these enterprises the government established two administrative systems. One was comprised by the competent departments for state-owned pharmaceutical enterprises. Another was the drug supervising system for drug quality control.

The competent departments were a series of administrative bodies assigned to represent the government to perform the function of ownership. The managers of state-owned pharmaceutical enterprises were responsible for management at the operational level, but decision-making and planning were performed by the competent departments of the government.

In order to supervise the quality of the work of the competent departments, China established a drug supervising system. This system belonged to the Ministry of health and its local branches. The employees were mainly responsible for the management of state-owned hospitals as well as quality control over pharmaceutical products. They had the authority to make regulations, set up national drug standards, approve grants and issue licenses.

2.3 The relationship between China’s competent departments and drug supervising agencies

Although China’s competent departments and drug supervising agencies were both responsible for the quality control over pharmaceutical products the ways in which they performed their functions were different.

The former took control of the quality and safety of pharmaceutical products by directly controlling the manufacturing process. The latter exercised control indirectly by making rules, granting new drug approvals and registration, and formulating national drug standards. The relationship between them is shown in figure 1.
These two systems have similarities and differences. They were both government agencies and had similar political principle of administrative practice. The former took charge of decision-making of state-owned pharmaceutical enterprises as well as quality control over pharmaceutical products produced by these enterprises. The latter took charge of decision-making of state-owned hospitals as well as quality control over the pharmaceutical products produced by pharmaceutical industry. Because there were two systems responsible for the quality control over pharmaceutical products this period was often characterized as the “double control” period.

On the surface China’s competent departments and drug supervising agencies were the regulators and pharmaceutical companies were the regulated. But they both had mixed functions. The regulators had incentives to run successful businesses. The
regulated companies and hospitals had political principles of practice similar to the regulators. The regulators and the regulated were so closely tied together that neither were independent. In addition, they both pursued political as well as economic goals. Pharmaceutical companies had little incentive to sacrifice the quality and safety for economic reasons.

We cannot find actual figures to illuminate the effect of the drug quality control system before 1977, but we can estimate its effects. From 1949 to 1977 China was isolated from the outside world. The standard of technology was very low, so the quality of drugs could not be very high. But the problems of counterfeit drugs were also likely to be rare because the enterprises had no incentive to produce them. The competent departments for pharmaceutical industry were likely to have held the main power to control the problems of counterfeit and inferior drugs where they were problematic. The drug supervising agencies that belonged to the Ministry of Health and its local branches lacked the necessary resources to do any effective oversight.

3 China’s drug regulatory system in early period of the reform policy (1978~1998)

Before the reform policy, the employees of government and state-owned enterprises viewed political outcomes as their major goals. The goals of economic development in many cases were neglected. This caused a period in which economic development slowed.

After 1978, China gradually followed a road to reform. Promoting the development of the economy became the primary goal of the government. China began a campaign to seek economic development under the command economy system.
3.1 China’s new competent departments for pharmaceutical industry

In the early period of the reform, many leaders of the country blamed the lack of integration amongst government departments for the slow development of the pharmaceutical industry. An effort was therefore launched to establish a centralized competent department for the whole pharmaceutical industry in 1978.

In 1978, the central government set up the Pharmaceutical Administration (PA), a new government agency aimed to organize the whole pharmaceutical industry and promote its development. But PA never grew to be a powerful organization, because it was faced with challenges associated with the decentralization reform carried out in the 1980s. The managers of state-owned enterprises eventually gained the power to make all the business decisions according to their own interests, so that the PA lost direct control over state-owned pharmaceutical enterprises. The government eventually allowed and even encouraged private capital to enter pharmaceutical businesses. Enterprises with different owners competed against each other and state-owned enterprises became weaker.

As this new reform progressed, pharmaceutical enterprises eventually lost all direct governmental control and became independent business entities. This new policy permitted these enterprises to become more active and competitive in the market, but unavoidably provided incentives for profit-driven pharmaceutical enterprises to sacrifice quality for money. To make matters worse, the PA, which supposedly was the competent department or the regulator of the pharmaceutical industry, received its financial support directly from the regulated pharmaceutical enterprises. This appeared to cause PA to lose its motivation and ability to control the quality of drugs. The drug supervising agencies affiliated to the Ministry of Health and its local branches remained weak, and could therefore not stop the decline in the quality of drugs. For the first time people found that China had no effective quality control system for pharmaceuticals.
The problems of fake or low quality drugs and illegal trade in pharmaceutical products became serious during this period.

A similar series of unfortunate consequences were also apparent in the health care system. Before 1978, all the hospitals and clinics were owned by the government or rural collective economic organizations which were very much like peripheral organizations of the government. The government took control of all of the money that hospitals and clinics earned and spent. Because they had no motivation to pursue profits, these institutions just followed the orders of the government without strong independent interests. The need to exert tight control over the quality of medicine in hospitals and clinics was not urgent.

After 1978, the government reduced its financial support of state-owned hospitals and clinics. Collectively owned clinics also lost financial support from rural collective economic organizations. After this reform hospitals and clinics became increasingly profit-driven. The low quality of drugs and medical services became a serious problem.

### 3.2 Main problems in early period of the reform policy (1978~1998)

The early period of the reform was not without positive results. From 1981 to 1985, the gross production of medical and pharmaceutical industry grew by 15% per year. From 1986 to 1990, the gross sales of drugs increased at the rate of 18.4% per year. By the end of the 1900s the growth rates were much higher than other sectors of China’s industry. The loss of direct governmental control freed the state-owned pharmaceutical enterprises to follow independent economic goals that resulted in rapid development and substantial revenue in private hands. However, these forces also had negative effects. The early period of the reform caused intense competition, disorder and substandard or even counterfeit drug production. In 1995, the number of pharmaceutical factories reached 5,300. There were more than 17,000 wholesale companies and 80,000 retail companies. Most of these factories and companies were
very small. During this period, the number of new drug applications increased substantially (only 10 in 1985 and 1,700 in 1997)\textsuperscript{10}, but very few were truly innovative\textsuperscript{11}. The quality of drugs was also declining.

4 Trials to establish an independent drug regulatory system (1998--)

Because of the serious side-effects of the early reform, calls for further reform became stronger and stronger from many parts of society.

The call for strengthening drug regulatory system appeared in the government work report of 1995 and 1996. In 1997, the State Council of China decided to establish an independent drug regulatory system. In 1998, the State Drug Administration (SDA), an agency directly affiliated to the State Council, was established, and the relationship between the regulatory agency and the regulated enterprises underwent great change\textsuperscript{12}. SDA was no longer responsible for promoting the development of the state-owned pharmaceutical enterprises which was the main mission of former Pharmaceutical Administration (PA). The newly established SDA was not allowed to take part in any profit-making activities\textsuperscript{13}. This reform marked the end of the unification of the regulator and the regulated. An independent drug regulatory system was established for the first time at least on paper.

SDA later changed its name to the State Food and Drug Administration (SFDA), and more recently adopted the new name of China Food and Drug Administration (CFDA) with an ongoing core mission to protect public health. In 2008 this agency lost its status of reporting directly to the State Council and became a part of the Ministry of Health but it regained this privilege in 2013. All of these changes in the status of the Chinese FDA have not changed the relationship between the agency and the regulated pharmaceutical industry. The independence of SFDA has continually strengthened. Beginning in 1998, government taxes began to fund the spending of this regulatory body, which would contribute to the independence of the agency. This reform also required SFDA to change the previous practices by which they regulate. It had to adopt
new regulatory tools suitable for the environment of the newly emerging market economy and consistent with international prevailing rules such as systems of technical standards and the administrative licensing.

![Figure 2: National sampling pass rates (%) for medicinal products from 1997-2013](image)

**Figure 2: National sampling pass rates (%) for medicinal products from 1997-2013**

*Relevant data is based on internet information of China’s CFDA*

The SFDA had not made much progress in the regulation of drugs before a series of corruption cases were exposed. The capture of regulation by the pharmaceutical industry was a serious problem, as illustrated by the serious corruption scandal that led to the execution of Zheng Xiao-yu, the former leader of SFDA. In spite of these challenges, China’s new system is widely thought to have brought remarkable improvement to the regulation of drugs. Looking back over the last 10 years, a series of guidelines, such as GMP, GSP, GLP and GCP, and many important regulations, such as the Reporting System of Adverse Drug Reactions and the Drug Recall System, all were introduced during this period. The quality of personnel and regulatory facilities of the agency have greatly improved. The quality of the drugs has also been improving. The percentages of qualified drugs in National Drug Evaluation Testing continued to rise (Figure 2).
5 Conclusions

Since the 1950s, almost all pharmaceutical enterprises and hospitals were operated directly by the government through its branches. This extensive control decreased the incentives for pharmaceutical enterprises and hospitals to make counterfeit drugs, so less need existed to monitor the safety and quality of drugs. The major defects of this system were its poor ability to foster dynamic innovation and growth. In order to promote the development of China’s pharmaceutical industry the government called for a reform to loosen direct governmental control over enterprises and hospitals in the late 1970s. This spurred the development of the pharmaceutical industry, but also created serious problems. The regulatory system was mainly concerned with the economic development of the industry and had no motive forces to supervise the quality and safety of drugs. As China transitioned to a market economy, the absence of independent regulatory system became serious.

The introduction of an independent regulatory system improved the regulator's capability to supervise the quality and safety of drugs. These increased regulatory resources have improved the quality of drugs. Nevertheless, the performance of China’s drug regulatory system is not entirely satisfactory. Many national or regional leaders of the government still hold that the growth of GDP is more important to their political promotion than the quality and safety of drugs. Impediments also exist inside China's drug regulatory system. Some officials of SFDA and its local branches still enjoy helping enterprises to promote their businesses overtly or covertly. The problem of regulation capture still exists and will be very difficult to solve.

The great difficulties that China experienced during the past 10 years have proven that the old ways in which the government regulatory agencies operate are very difficult to shake. The policy maker should fully understand the impact of the previous system and make a disciplined and coordinated effort to intervene in those areas that are most problematic. The best way to establish a good independent drug regulatory system has to be a gradual rather than a radical reform.
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