An Exploration of Improving the Regulatory System for Online Pharmacy Based on New Policy

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Abstract

Objective To analyze the current situation of drug regulation after introducing the new policy for China's online pharmacy, and to provide reference for the regulation of online pharmacy based on the international experience. **Methods** Through literature research and comparative analysis, the history of policies for online pharmacy in China was investigated, and the current situation and problems of regulation for online pharmacy were explored. **Results and Conclusion** It is found that the body, basis and behavior of online prescription drug supervision in China should be improved. Combining experience in regulating online prescription drug at home and abroad, we provide some suggestions for the implementation of China's online prescription drug policy by establishing a government-led multiple regulatory mechanism, standardizing the access qualifications for enterprises with business in online prescription drugs, improving the prescription inquiry and review system, and paying attention to consumer needs.

Keywords: online sale of prescription drug; drug regulation; policy

As e-commerce officially kicked off in 1998, the world's first online drugstore was created by Smith, an American businessman. Since then online pharmacy has come into being [1]. In China, the market for online pharmacy did not open until the introduction of the "Interim Provisions for the Approval of Internet Drug Trading Services" in 2005 [2]. Due to the uncertainty, variability and risk of prescription drugs, the online sale of prescription drugs has always been a hot topic for the drug retail industry [3]. Until May 2014, the "Measures for Supervision and Administration of Internet Food and Drug Administration (Draft)" first proposed that prescription drugs could be sold online. Then, the new version of the "Drug Administration Law of the People's Republic of China" was formally passed in 2019, which means prescription drugs can be purchased online. General Secretary Xi pointed out that "drug safety should be given top priority". As special commodities, the safety and quality of drugs are concerned by the public. The Internet era brings not only opportunities but also great challenges to drug regulation [4].

1 History of supervision policy for online sale of prescription drugs

Since drugs are extremely risky, they can directly

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affect the lives and health of the people. China's drug regulators have always been hesitant to allow prescription drugs to be sold online because they have more particularity, risk and demand than non-prescription drugs. With the continuous penetration of the Internet and the popularity of the COVID-19, the online prescription drug sale has finally been permitted by the government after more than a decade. The laws and regulations related to the online sale of prescription drugs that are sorted out through the official website of the National Medical Products Administration and the Central People's Government of the People's Republic of China are shown in Table 1.

Table 1 Laws and regulations related to online sale of prescription drugs

Release time	Filename	Legal level	Related points
December 1999	Interim Provisions on the Circulation Administration of Prescription Drugs and Non-Prescription Drugs	Normative documents	Prescription and non-prescription drugs are not allowed to sell online, and the pilot terminated
February 2000	Guiding Opinions on the Reform of the Urban Medical and Health System	Normative documents	Purchase and sell drugs actively make use of modern electronic information network technology
June 2000	Measures for the Supervision and Administration of the Pilot Drug E-commerce	Normative documents	Relaunch of the pharmaceutical e-commerce pilot
September 2002	Regulations for the Implementation of the Drug Administration Law	Administrative regulations	Drug trading through the Internet must comply with the provisions of the "Drug Administration Law" and these regulations
July 2004	Administration of Internet Information Services Procedures	Departmental regulations	Drug regulatory department shall implement pre-approval procedures, requirements and corresponding supervision measures for the departments engaged in Internet drug information services
October 2005	The Provisional Regulations Concerning Drug Information Service on Internet	Normative documents	Implement examination and approval management for Internet drug transactions, and companies providing the service can only sell non-prescription drugs online
January 2007	Provisions for Supervision and Administration of Drugs	Departmental regulations	Specify that drug manufacturers, business enterprises and medical institutions are not allowed to sell prescription drugs directly to the public by mail, self-dealing or the Internet
May 2014	Provisions for Supervision and Administration of Internet Foods and Drugs (Draft)	Departmental regulations	Drug trading enterprises shall sell prescription drugs to individuals online by prescription in accordance with the requirements of drug classification and administration
April 2017	Decision of the Third Batch of the State Council on the Elimination of Administrative License Items designated by the Central Government	Normative documents	Internet drug trading enterprises have approved and filed records, and pointed out that prescription drugs shall not be sold online and shall not be displayed on the pages of relevant trading websites
November 2017	Provisions for Supervision and Administration of Online Drug Sales (Draft)	Departmental regulations	Clear that prescription drugs shall not be sold online
February 2018	Provisions for Supervision and Administration of Online Drug Sales (Draft)	Departmental regulations	Online sales of prescription drugs to individual consumers are still temporarily banned

(to be continued)

Continued Table 1

Release time	Filename	Legal level	Related points
April 2018	Opinions on Promoting the Development of "Internet + Medical Health"	Normative documents	Clearly put forward that prescription issued online, after pharmacist review can be delivered by qualified third parties
December 2019	Drug Administration Law of the People's Republic of China	Laws	Cancel the contents of the "Drug Administration Law (Revised Draft)" (the second draft) that shall not directly sell prescription drugs through the Internet or third-party platforms, and clearly stipulates that drugs can be sold online, and there is no ban on online prescription drugs
November 2020	Provisions for Supervision and Administration of Online Drug Sales (Draft)	Departmental regulations	Offer to sell some prescription drugs online
April 2021	Opinions on the "six stability" and "six guarantees" to further improve the reform of "delegating power, delegating power and service"	Normative documents	Clearly stated that the online sales of prescription drugs except for drugs under special administration by the State are allowed on the premise of ensuring the true and reliable sources of electronic prescriptions
May 2022	Regulations on the Implementation of the Drug Administration Law of the People's Republic of China (Draft Revision for Comments)	Regulatory documents	For the clear provision of online prescription drugs, the source of prescriptions is true and reliable, and can be deployed after examination
August 2022	Provisions for Supervision and Administration of Online Drug Sales	Departmental regulations	Clear requirements are made for drug online sales enterprises and third-party platforms, and it stipulates that online sales of prescription drugs should ensure that the source of prescriptions is authentic and reliable with implementing a real-name system

Although the online shopping started in 1998, China's government completely banned the sale of drugs online. However, with the introducing of a new policy, OTC drugs could be sold online in 2000. In 2014, the "Measures for the Supervision and Administration of Internet Drug Distribution (Draft)" put forward the sale of prescription drugs online for the first time, which means the preparation for online sales of prescription drugs. Until 2019, after the promulgation of the new "Drug Administration Law of the People's Republic of China", the online sale of prescription drugs entered a new era.

It is an inevitable trend to release the ban of prescription drugs online. On the one hand, the online sale of prescription drugs can solve the disadvantages in the pharmaceutical circulation system, such as selling drugs to support doctors and inconvenient drug purchase. The Internet can make drug prices transparent, which breaks the pattern of layer price increase and alleviate the patients' psychology of expensive medication [5]. On the other hand, since the aging of China's population is serious, the prevalence of chronic diseases such as hypertension and diabetes has increased rapidly. As a result, the market demand for prescription drugs is also increasing year by year. The convenience of online sale of prescription drugs is reflected in the fact that patients can avoid cumbersome processes such as registration, queuing, and picking up drugs, which can also reduce the economic burden of patients to a certain extent [6-8].

Although online prescription drugs has many advantages, the biggest problem of online prescription drugs lies in the safety and authenticity of drugs, which is also a big drawback of the Internet concealment and virtual nature. It is one of the reasons why the policy for online sale of prescription drugs has not been introduced. In order to open the market of online prescription drugs, drug regulatory authorities also

need to constantly improve the supervision system to ensure the safety of patients who buy prescription drugs through the Internet. Therefore, consolidating the foundation of online prescription drugs is the top priority to lifting the ban on online sale of prescription drugs.

2 Current situation and problems of drug supervision after introducing the new policy for online sale of prescription drugs

2.1 Current situation of drug supervision after introducing the new policy for online sale of prescription drugs

In recent years, the drug regulatory authorities have undergone two major reforms. In 2013, the drug supervision was reformed from the vertical supervision and management system to the local supervision by food and drug supervision and management institutions affiliated with at all levels of government. In March 2018, through the three-in-one institutional reform, the market supervision and administration department was established. Due to the particularity of drugs, the National Drug Administration came into being, which is managed by the State Administration for Market Regulation. However, the drug regulatory authorities were only set up at the provincial level. Because Internet is the channel for the online sales of drugs, in addition to the drug regulatory departments, market supervision and administration departments and the public security department are involved. Table 2 lists the specific supervisory departments and their responsibilities [4].

Table 2 Online drug sales regulatory departments and their responsibilities

Regulatory department	Regulatory responsibility
Market supervision and administration department	Responsible for developing standards and regulatory systems for drugs entering the Internet market, penalizing violations that occur during the online sale of drugs, responsible for regulating drug prices and advertising in the Internet market
Internet information authority	Responsible for policy guidance, industry regulation and coordination of electronic transactions through the Internet and regulation of websites
Public security organization	Responsible for investigating and punishing offence relating to the sale of drugs on the Internet market
Postal department	Regulatory authority for distribution companies

As can be seen from Table 2, there is no regulatory department specifically responsible for supervising prescription drugs, which is one of the defects of drug supervision in China. In addition to the regulatory subject, the regulatory basis and supervision means are also very important. “Measures for Supervision and Administration of Online Drug Sales” clearly put forward the conditions for online sales of prescription drugs, which also standardized drug online sellers and third-party platform providers from the four aspects such as online sales management, platform management, supervision and legal responsibility. As the policy for online prescription drug sale has just been introduced, the regulatory system established in this respect is still insufficient. China’s drug regulatory authorities should pay more attention to the online sale of prescription drugs.

2.2 Problems with drug supervision after introducing policy for online sale of prescription drugs

2.2.1 Single regulatory body and insufficient collaboration among industry associations

Although there are many regulatory departments for drugs in China, they all belong to government in nature, which shows that the feature of single

regulatory body. Drug distributors have also actively established relevant pharmaceutical industry associations, but due to their immature development, they cannot play a role as a bridge between the government and enterprises. In addition, the huge number of regulatory objects and the chaotic prescription drug network channels bring many burdens for supervision. Besides, the single regulatory body also leads to many difficulties in supervision.

2.2.2 Difficulty in guiding the work due to backward regulatory policies

The "Measures for Supervision and Administration of Online Drug Sales (Draft)" mentioned the permission of the online sale of prescription drugs in 2020. It was officially issued in August 2022, which was officially implemented in December. From 2020 to 2022, the online sale of prescription drugs was in the government acquiescence stage because it was neither banned nor wantonly supported. The online sale of prescription drugs is in the empty window period of the policy, and enterprises with the online prescription drugs are still in the test stage. However, the online sale of prescription drugs is the inevitable trend of social development. Now, the regulatory measures have been formally issued, and the regulatory authorities should take up their responsibility for the online sale of prescription drugs.

2.2.3 Weak regulatory force and investigation intensity

Online sale of prescription drugs has been allowed, but due to the lack of regulatory laws and regulations, the phenomenon of illegal online sales of prescription drugs occurs from time to time in China. Because of the imperfect laws and regulations, the prescription drug network management enterprises can operate improperly. It reflects the weakness of China's online prescription drug regulatory force. Besides, it is difficult to effectively investigate and deal with illegal behavior of online prescription drugs sales.

2.2.4 Insufficient regulatory mechanism and problems in service system

The regulatory mechanism needs to run through all aspects of the online sale of prescription drugs. At present, online prescription drugs are in the early stage of development in China. Although several relevant policies were introduced such as the real-name system and the measure of prescription first. Besides, the regulatory mechanism should be continuously improved in the process of selling prescription drugs online. First, the logistics distribution is a major problem for the regulatory authorities because prescription drugs have stricter requirements for the distribution and storage. Imperfect logistics distribution system cannot guarantee the quality of drugs, so supervision should focus on drug circulation. Secondly, it is necessary to strengthen the integration of the legal mechanism, which includes the social control mechanism and the self-discipline mechanism. The sales subjects should spontaneously abide by the laws and regulations. In addition, the regulatory departments should strictly implement the supervision system, and the social public can also actively practice the supervision responsibility, which will promote the benign development of the online prescription drugs.

There is the problem of uneven distribution and insufficient number of licensed pharmacists. Some pharmacies have not yet met the requirements of having enough licensed pharmacists. It is even worse for online pharmacies. If the online sale of prescription drugs cannot receive professional pharmaceutical guidance, it will increase the risk of using prescription drugs. Therefore, we should pay more attention to pharmaceutical care online.

3 Foreign supervision experience for reference in online sale of prescription drugs

As the United States, Britain and Germany started online pharmacy earlier, the regulatory system for online prescription drug is relatively complete, and each country has the unique regulatory model. The

United States has pluralistic characteristics, the British corporatism is the expression of the relationship between the state and society, and Germany emphasizes the supremacy of the state interest. This paper draws on the experience of regulatory practice combing with the regulatory models from these countries.

3.1 American supervision experience of online sale of prescription drugs

Pluralism in the United States extends to the field of regulation of online sale of prescription drugs. It attaches great importance to the multi-party governance of government departments, industry associations and social organizations. As it has a clear division of responsibilities and close collaboration among regulatory authorities, it can achieve the purpose of joint supervision [9, 10]. In addition, online pharmacies in the United States follow a strict admission system. Meanwhile, the separation system has promoted the development of prescription drugs online. The leadership of online prescription drugs in the United States cannot be separated from the legislative protection at the national level and the development of the insurance industry. Meanwhile, the legalization of online diagnosis and treatment, the prescription right of pharmacists and the network infrastructure also promote the formation and general recognition of online prescription drugs to a certain extent [6]. The US regulatory subject, regulatory basis and regulatory behavior are all relatively perfect, which can play an important role in regulating online sale of prescription drugs.

3.2 British supervision experience of online sale of prescription drugs

British regionalism emphasizes the integration of social interests and national decision-making, maintaining the positive interaction for a long time [11, 12]. The regulatory system in the UK is also relatively mature, which has a clear regulatory body, and the regulation of advertising is also included. Online pharmacies in the UK are also very strict, and they must register with the Royal Pharmaceutical Society of Great Britain (RPSGB) to obtain the qualification of selling prescription drugs online. To reduce the illegal behavior of selling prescription drugs online, the UK has implemented the online pharmacy logo program. The UK has more advanced regulatory methods, breaking the restriction of buying prescription drugs online by prescription photocopying and legally dispensing prescriptions through online pharmacies. At the same time, the UK pays more attention to the education of consumers' online shopping of prescription drugs. For example, it conducts "cyber day" surveys and publicizes the illegal sale of prescription drugs through various media, thereby warning consumers.

3.3 German supervision experience of online sale of prescription drugs

Germany's national will is detached from social interests, and only state-led online pharmacies can sell prescription drugs online [13-15]. At the same time, online pharmacies need to pass the certification and conduct supervision and inspection every year. After three years, online pharmacies also need to be re-evaluated to get the certification. Therefore, Germany's requirements for access qualification are not weaker than those of the UK and the US. Germany has made strict rules on drug distribution at online pharmacies, ensuring that prescription drugs can be delivered to customers within 48 hours after completing their orders. The government also has set up a pharmacy inspection system to severely punish illegal online sales of prescription drugs.

4 Countermeasures to improve the regulation of online sale of prescription drugs in China

From the foreign experience of online prescription drug supervision, we can see the supervision focuses on the qualification access, prescription review and online

services of pharmacists. China has some problems in these areas, which is also the reason for the delay in lifting the ban on online prescription drugs. Now that the new policy for prescription drugs has been introduced, it is urgent to improve China's online prescription drug supervision system. Therefore, we can draw experience from the mature regulatory model abroad, and then put forward countermeasures and suggestions to solve the problems in the supervision of online prescription drugs in China.

4.1 Establishing a government-led diversified regulatory mechanism

China's drug regulatory body is relatively single. From the regulatory body in the United States, we can see that the mutual cooperation between the government, the market and the society is vital. The British government and the association of the benign interaction is also maintained for a long time. Although online pharmacies in Germany are dominated by the government, they also need the strong support of social insurance. Therefore, the establishment of the government-based multi regulatory mechanism is necessary, while the government regulatory process can play an organizational role so that various regulatory departments can work together.

4.2 Establishing a sound regulatory system and standardizing access qualifications

The US, the UK and Germany have basic laws and industry regulations for the supervision of online sale of prescription drugs. However, China has not perfected its regulations for online sale of prescription drugs after the introduction of the new version of the "Drug Administration Law of the People's Republic of China", which shows the backwardness of China's regulatory system and the lagging regulatory policy. It results in the lack of access to enterprises and third-party platforms. Therefore, the introduction of relevant rules and regulations as soon as possible to regulate the access of enterprises is the basic premise for the start of online prescription drugs.

4.3 Establishing an online prescription inquiry and audit system to strengthen the investigation and punishment

One of the difficulties faced by the online sale of prescription drugs is that customers are hard to identify the authenticity of prescription drugs. We can learn from the experience of Britain and the United States to establish a prescription information sharing platform. Firstly, prescriptions can be generated on the two-dimensional code. Then, patients can check the prescription information online to ensure that the prescription is true. At the same time, China still needs to strengthen the investigation and punishment, the illegal online sale of prescription drugs should be prohibited. If there is a violation, they will be punished severely, which can reduce the risk of illegal prescription drugs.

4.4 Focusing on consumer protection and service needs

The analysis of the regulatory systems in the UK, the US and Germany shows that the protection of consumer rights is particularly important. The United States emphasizes consumer safety education and supervision, and the government adopts a variety of methods to remind consumers of the risks of purchasing drugs online. The UK conducts special investigation actions and case warning education through "cyber day". Germany relies on strong social insurance as a regulatory support, and it requires consumers to be able to distinguish the authenticity of drugs, consumers will also pay more attention to the authenticity of prescription drugs out of their own consideration.

China should learn from the experience of foreign countries, pay attention to the protection of the rights and interests of patients buying prescription drugs online. Therefore, the government should improve the protection mechanism of consumer rights and interests, and the awareness of consumers buying prescription drugs online. At the same time, China should also improve the level of online services

of licensed pharmacists, standardize the duties of licensed pharmacists. They not only review the prescriptions, but also give patients guidance on the use of drugs, which can improve patients' satisfaction with the drugs they buy online.

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