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Problems and Countermeasures in Medical Management and Supervision

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Abstract: The management and supervision of medicine is the key link to protect public health, maintain the order of medicine market and promote the sustainable development of medicine industry. However, at present, China's pharmaceutical management and supervision still faces many challenges, such as imperfect laws and regulations system, insufficient supervision power and professional ability, inadequate implementation of corporate main responsibility, information supervision level to be improved, and imperfect social supervision mechanism. These problems not only threaten the life and health of the public, but also restrict the healthy development of the pharmaceutical industry. In order to meet these challenges, this paper puts forward a series of systematic countermeasures, including perfecting the legal system, strengthening the construction of supervision force, implementing the main responsibility of enterprises, improving the level of information supervision and improving the social supervision mechanism. Through the implementation of these measures, it aims to build a more scientific, efficient and transparent medical management and supervision system to protect the health of the people.

1. Introduction

In today's society, the management and supervision of medicine is not only an important line of defense to protect public health, but also a key link to maintain the order of the medical market and promote the healthy development of the pharmaceutical industry. With the continuous progress of medical technology and the growing prosperity of the medical market, the types and quantities of medical products have increased dramatically, and the complexity and professionalism of its production, circulation and use have become increasingly prominent [1]. However, at the same time, the management and supervision of medicine are also faced with many challenges and problems, such as drug quality and safety risks, false propaganda and illegal sales, uneven distribution of medical resources, and imperfect medical supervision system. These problems not only threaten people's lives and health, but also restrict the sustainable development of the pharmaceutical industry [2].

In the face of these severe challenges, how to effectively identify and solve the problems in medical management and supervision has become an important issue that needs to be overcome urgently. The purpose of this study is to deeply analyze the main problems existing in the current medical management and supervision. On this basis, this paper will focus on a series of highly targeted and operable countermeasures, aiming at building a more scientific, efficient and

transparent medical management and supervision system.

2. Analysis on the current situation of medical management and supervision

In recent years, China's drug regulatory system has been continuously reformed and improved, and a regulatory framework covering national, provincial, municipal and county levels has been established, realizing the supervision of drugs throughout their life cycle. Relevant laws and regulations, such as Drug Administration Law, Chinese Medicine Law and Vaccine Administration Law, have been promulgated one after another, providing a solid legal basis for supervision. At the same time, by strengthening team building, improving technical evaluation ability, optimizing law enforcement system and promoting information construction, such as drug traceability and pharmacovigilance system, the supervision ability and efficiency have been continuously improved [3].

However, the current regulatory work still faces many challenges. The number of supervisors in some areas is insufficient and their professional quality is uneven, which affects the effect of law enforcement. The update of drug regulatory standards is lagging behind, which makes it difficult to adapt to the rapid development of medical technology. Traditional supervision methods are also backward, and innovative ways are urgently needed to improve efficiency. In addition, drug safety involves a wide range, and systemic risks are prominent, which requires coordinated governance by the government, enterprises, society and the public.

3. Core problems in medical management and supervision

As a key link to ensure the safety of public drug use and maintain the order of the pharmaceutical market, pharmaceutical management and supervision plays an irreplaceable role in promoting the healthy development of the pharmaceutical industry and ensuring people's lives and health. However, with the rapid development of the pharmaceutical industry and the increasingly complex market environment, pharmaceutical management and supervision are facing many challenges, exposing a series of core problems, which seriously affect the orderly development of the pharmaceutical industry and the safety and effectiveness of public medication.

3.1. The system of laws and regulations is not perfect

At present, although the laws and regulations related to medical management in China have formed a certain system, there are still many loopholes and shortcomings. Some laws and regulations are general and lack clear implementation rules and operating standards, which leads to differences in the understanding and implementation of laws and regulations by law enforcement personnel in the actual supervision process. Taking the supervision of drug advertisements as an example, the Drug Administration Law has prohibitive provisions on false drug advertisements, but it lacks detailed provisions on the definition of the authenticity of advertising content and the punishment standard for illegal advertisements, which makes some enterprises take advantage of the legal loophole and publish drug advertisements that exaggerate the curative effect and mislead consumers [4]. With the rapid development of medical science and technology, such as gene therapy, cell therapy and other emerging fields, the existing laws and regulations are lagging behind in these aspects, which can not provide sufficient legal basis for supervision in time, resulting in the passive state of supervision.

3.2. Lack of supervision and professional ability

The management and supervision of medicine involves many links such as drug research and development, production, circulation and use, with a wide scope of supervision and heavy tasks, but the supervision power is obviously insufficient at present [5]. According to relevant statistics, the proportion between drug supervisors and the number of pharmaceutical production and operation enterprises in China is seriously unbalanced, especially among grass-roots regulatory agencies. Take a province as an example, there are thousands of pharmaceutical production and operation enterprises in the province, but only a few hundred professionals are in charge of daily supervision. Faced with a huge supervision object, it is difficult to conduct comprehensive and meticulous supervision and inspection. The professional ability of supervisors is uneven, and some supervisors lack medical professional knowledge and practical experience, so it is difficult to accurately judge and effectively supervise in the face of complex drug quality problems and emerging medical technologies. In the field of medical device supervision, some grass-roots supervisors have limited understanding of the principle, performance and quality standards of high-end medical devices, which affects the quality and efficiency of supervision.

3.3. The implementation of corporate main responsibility is not in place

Some pharmaceutical enterprises are driven by interests, ignoring drug quality and safety, and have a weak sense of main responsibility. In the pharmaceutical production process, some enterprises change the production process and use unqualified raw materials without authorization in order to reduce costs and violate the production quality management norms; In the circulation of drugs, some enterprises have some problems, such as purchasing drugs illegally and the storage conditions of drugs do not meet the requirements [6]. A pharmaceutical company used inferior raw materials to produce drugs, which led to many adverse reactions; A pharmaceutical wholesale enterprise purchased drugs from illegal channels for personal gain, which disturbed the normal order of the pharmaceutical market. These behaviors not only harm the health rights and interests of consumers, but also have a negative impact on the reputation of the pharmaceutical industry.

3.4. The level of informatization supervision needs to be improved

In the digital age, medical management and supervision work is increasingly dependent on information technology, but at present, the informatization construction of medical supervision in China is relatively backward. The lack of effective integration and sharing of regulatory information systems among various regions and departments has formed an information island, and it is impossible to realize the interconnection and collaborative supervision of regulatory data. The production data of pharmaceutical production enterprises, the operation data of circulation enterprises and the usage data of medical institutions are scattered in different systems, so it is difficult for the regulatory authorities to fully grasp the whole life cycle information of drugs and find and deal with potential quality and safety problems in time [7]. In addition, the application of information supervision means is not deep enough, and the application of advanced technologies such as big data and artificial intelligence in medical supervision is still in its infancy, which fails to give full play to its advantages in risk early warning and precise supervision.

3.5. The social supervision mechanism is not perfect

The management and supervision of medicine need the participation of the whole society, but the social supervision mechanism is not perfect at present. The public has limited knowledge of

medicine and lacks the ability to identify drug quality problems and irregularities, which makes it difficult to give full play to the supervisory role of the pharmaceutical market. The reporting channels are not smooth enough, and the protection and reward mechanism for informants is not perfect, which affects the enthusiasm of the public to participate in supervision. Although media supervision has played a certain role in medical supervision, due to the lack of professional medical knowledge and in-depth investigation ability, some media reports are one-sided and misleading and fail to accurately reflect the real situation of the medical market.

The core problems in medical management and supervision seriously restrict the healthy development of the pharmaceutical industry and the safety of public medication. Only by facing up to these problems, taking targeted measures to solve them, constantly improving the legal and regulatory system, strengthening the construction of supervision force, strengthening the main responsibility of enterprises, improving the level of information supervision and improving the social supervision mechanism, can we build a scientific, efficient and perfect medical management and supervision system and protect the health of the people.

4. Systematic countermeasures and suggestions

In view of the problems existing in the management and supervision of medicine, it is necessary to construct a set of systematic countermeasures to ensure the safety of public medication, maintain the order of the pharmaceutical market and promote the healthy development of the pharmaceutical industry.

4.1. Improve the system of laws and regulations

Government regulatory authorities should continue to pay attention to the new development and new demand in the field of medicine, and timely bring emerging technologies and business models into the scope of legal supervision. For example, for frontier fields such as gene therapy and cell therapy, medical experts and legal experts should be organized to conduct in-depth research, formulate special laws and regulations or revise existing laws and regulations, and clarify regulatory principles, standards and procedures to provide a solid legal basis for regulatory work.

In view of the general provisions of laws and regulations and the lack of clear implementation rules and operating standards, relevant laws and regulations should be further refined. Taking drug advertising supervision as an example, we can learn from international advanced experience and formulate detailed criteria for defining the authenticity of advertising content and detailed rules for punishing illegal advertisements. Specifically, it can include standardizing advertising terms and explicitly prohibiting the use of words that exaggerate curative effect and mislead consumers; According to the severity of advertising violations, different levels of punishment standards are set, such as warning, fine, revocation of advertising qualification, etc., and the corresponding fine amount range is clear.

4.2. Strengthen the construction of supervision power

(1) Enrich the supervision team

According to the reasonable proportion between the number of pharmaceutical production and marketing enterprises and the number of supervisors, a scientific staff expansion plan shall be formulated. Relevant departments should increase the number of personnel in grass-roots regulatory agencies through recruitment of civil servants and career establishment. Excellent talents can be selected from college graduates majoring in medicine to enrich the supervision team and inject fresh blood into the supervision work.

(2) Enhance professional ability

Regularly organize supervisors to participate in professional training, which covers medical professional knowledge, laws and regulations, supervision skills, etc. For the supervision of high-end medical devices, industry experts are invited to give lectures, so that supervisors can deeply grasp its principle, performance and quality standards. We can also establish a practical training mechanism for supervisors, and send supervisors to pharmaceutical enterprises and scientific research institutions for post-employment training, so as to enhance their perceptual knowledge of drug production and circulation and improve their actual supervision ability.

4.3. Implement the main responsibility of enterprises

In order to solve the problem that the main responsibility of enterprises is not implemented in place, the following measures are taken:

(1) Strengthen supervision and inspection

The supervision department should strengthen the supervision and inspection of the production and circulation of enterprises. For example, regular flight inspection of pharmaceutical production enterprises, focusing on the implementation of production quality management norms, including whether the production process is changed without authorization, whether the raw materials are qualified, etc. Enterprises that violate the rules will be severely punished according to law, and ordered to make rectification within a time limit. Enterprises that fail to make rectification can take measures such as stopping production and rectifying.

(2) Establish enterprise self-inspection mechanism

Relevant departments should guide enterprises to establish a sound quality management system and self-inspection mechanism. Enterprises should regularly conduct self-inspection on their own production and business activities, find problems and rectify them in time, and submit the self-inspection report to the regulatory authorities for the record. The regulatory authorities can conduct spot checks on the self-inspection of enterprises, and conduct informed criticism on enterprises that are not serious and perfunctory in their self-inspection work and are listed as key regulatory targets.

(3) Improve the credit evaluation system

Relevant legislative bodies should establish and improve the credit evaluation system of pharmaceutical enterprises, and include illegal acts, product quality, self-examination and self-correction into credit evaluation indicators. According to the results of credit evaluation, enterprises with different credit ratings are subject to classified supervision. Government supervision departments should give policy support to enterprises with good credit and reduce the frequency of inspections and other incentives; Strengthen the supervision of enterprises with poor credit, restrict their participation in bidding, procurement and other market activities, increase their illegal costs, and urge enterprises to consciously implement the main responsibility.

4.4. Improve the level of information supervision

Relevant departments should break the information islands between regions and departments and establish a unified medical supervision information platform. Integrate the production data of pharmaceutical production enterprises, the operation data of circulation enterprises and the usage data of medical institutions to realize the interconnection and collaborative supervision of regulatory data. Through the information platform, the regulatory authorities can grasp the whole life cycle information of drugs in real time, and find and deal with potential quality and safety problems in time. The government supervision department should establish a drug database, including detailed information such as drug composition, curative effect, manufacturer and approval

number. The relevant departments should establish a database of regulatory objects to record the basic information, production and operation qualifications and regulatory history of pharmaceutical enterprises. Through the establishment of the database, it is convenient for supervisors to inquire and compare, and the supervision efficiency is improved. In-depth application of advanced technologies such as big data and artificial intelligence to improve the efficiency of information supervision. Using big data analysis technology, the data of adverse drug reactions, complaints and reports are analyzed and mined, and the risk signals of drug quality and safety are found in advance. With the help of artificial intelligence algorithm, the intelligent monitoring of drug production and circulation links can be realized, and illegal operation behaviors can be automatically identified, and timely early warning can be notified to the regulatory authorities for handling.

4.5. Improve the social supervision mechanism

Government supervision departments should strengthen the popularization of medical knowledge to the public. Relevant departments should spread the knowledge of drug safety and rational drug use through community propaganda, media reports, online platforms and other channels, make popular and easy-to-understand popular science videos and broadcast them on TV and online platforms, organize experts to give lectures in the community, answer public questions, enhance the public's understanding of medical knowledge, and strengthen the ability to identify drug quality problems and illegal acts.

The government should establish convenient reporting channels, such as special hotline, e-mail address and online reporting platform, to ensure its stability and reliability. For example, the relevant departments should designate a special person to answer the phone and process the information, check and process the contents of the report in time, and give feedback to the informants to ensure that the reporting channels remain smooth and effective.

The government supervision department should improve the whistleblower protection and reward mechanism, strictly keep the whistleblower information confidential and prevent retaliation. The relevant departments should provide certain rewards for whistleblowers, such as bonuses and honorary certificates, enhance the enthusiasm of the public to participate in supervision. Strengthen the training of media medical knowledge, improve the professional quality of media and the ability of investigation and reporting. When reporting medical-related events, the media should follow the principles of objectivity, fairness and accuracy, and avoid one-sided and misleading reports. Regulatory authorities can establish a regular communication mechanism with the media, timely inform the media about the work of medical supervision, and guide the media to correctly play a supervisory role.

5. Conclusion

In the management and supervision of medicine, although China has established a relatively perfect regulatory framework and legal system, there are still many problems. Imperfect laws and regulations system, insufficient supervision power and professional ability, inadequate implementation of corporate main responsibility, imperfect information supervision level and imperfect social supervision mechanism are the main challenges currently facing. In order to deal with these problems, the study put forward a series of systematic countermeasures. First of all, it is necessary to improve the system of laws and regulations, bring emerging technologies and business models into the scope of legal supervision in a timely manner, and refine relevant laws and regulations to clarify the implementation rules and operating standards. Secondly, we should strengthen the construction of supervision force, and enrich the supervision team by increasing the number of personnel in grass-roots supervision institutions and improving the professional ability of

supervisors. At the same time, it is necessary to implement the main responsibility of enterprises, strengthen supervision and inspection, establish a self-inspection mechanism for enterprises, and improve the credit evaluation system. In addition, it is necessary to improve the level of information supervision, break the information island, establish a unified medical supervision information platform, and deeply apply advanced technologies such as big data and artificial intelligence. Finally, we should improve the social supervision mechanism, increase the popularization of medical knowledge among the public, establish convenient and smooth reporting channels, improve the protection and reward mechanism for informants, and strengthen the medical knowledge training of the media. By implementing these comprehensive measures, we can build a more scientific, efficient and transparent medical management and supervision system, thus effectively ensuring the safety of public medication, maintaining the order of the pharmaceutical market and promoting the healthy development of the pharmaceutical industry.

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