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The Problems and Difficulties of Medical Devices in Chongqing in Response to Public Health Incidents in 2022

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Abstract

Background and Aim: In the face of emergencies such as large-scale infectious diseases, some medical device manufacturers either do not have enough practical research and development experience in related epidemic prevention medical devices or use cheaper raw materials to reduce product quality in the research and development stage to save costs and increase profits. purpose, and even use various channels and means to bypass market supervision and produce problematic medical devices from the very beginning. Or, to take advantage of the public's panic about unknown infectious diseases, some unscrupulous merchants falsely advertise products that do not meet medical requirements, confusing the masses without certain professional cognitive ability, blindly believing and following them, and causing sudden large-scale infectious diseases. It cannot effectively reduce and contain the spread of diseases or other public health events. Infectious diseases spread rapidly in various cities. This is the problem with the quality supervision of medical devices under public health emergencies. From this new crown pneumonia epidemic, it can be found that the existing system is still unable to meet the needs of emergencies such as public health. It is necessary to do a good job of system reserves for the accessibility of drugs and medical devices from the level of laws and regulations. This needs to be sorted out to achieve accessibility. The existing regulations and systems should be improved to meet the needs of medical device use in public health and other emergencies.

Materials and Methods: Safety testing of medical devices used in 26 public health events using Chinese national standards

Results: The histogram of sample scores in the operation link reveals a complex landscape with an increased sample size. This data accentuates the intricate scoring dynamics and intricate qualification rates within the operation link, showcasing variations even among identical products from the same manufacturer. The case of "LFR20B" and "LFR30B" infrared forehead thermometers exemplifies how subtle factors, such as the weighting of specific performance indicators, contribute to scoring distinctions. Despite the "LFR20B" model achieving a higher score, it falls short of the category's passing threshold, underscoring the intricate nature of sample evaluations. However, it is noteworthy that 58% of the samples successfully meet national standards and pass the inspection, indicating a substantial portion complying with regulatory requirements.

Conclusion: Laws and regulations need to be improved, there are hidden dangers in regulation, the ability of regulatory teams needs to be improved, medical device enterprises have problems, medical devices should strictly follow national standards, and the public should actively participate in medical device regulation.

Keywords: Public Health; Medical Equipment; Quality Problem; Inspect; Improving the System

Introduction

Taking the novel coronavirus pneumonia epidemic that raged across the country starting in January 2020 as an example, in the face of this infectious disease that spreads quickly, has a large scale of infection, and seriously threatens public health, research and development and selection of medical devices for the prevention and treatment of new crowns, and making it available quickly through green channels is an important prevention and control measure. However, medical devices cannot fully meet clinical needs due to factors such as long research and development and inspection cycles, wide applicable standards, insufficient production capacity, and cumbersome review processes. To cope with the shortage of medical devices caused by public health emergencies such as new crown pneumonia, it is necessary to improve the inspection, review approval, and listing systems, and to standardize the emergency use system under special circumstances.

In 2022, Chongqing, China, faced a series of public health incidents, including outbreaks of COVID-19, hepatitis E, and hand, foot, and mouth disease. These incidents highlighted the importance of having a robust medical device industry to support public health preparedness and response. However, the Chongqing medical device industry faces several problems and difficulties, which can hinder its ability to respond effectively to public health emergencies. The following are some of the key problems and difficulties facing the Chongqing medical device industry: (1) Limited

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innovation: The Chongqing medical device industry is still relatively young and lacks the innovation capabilities of more developed regions. This can lead to a shortage of new and innovative medical devices that are needed to address public health challenges. (2) Low quality: Some medical devices produced in Chongqing are of low quality, which can put patients at risk. This is due to several factors, including a lack of quality control, poor manufacturing practices, and the use of substandard materials. (3) Inadequate regulation: The regulatory framework for medical devices in Chongqing is not as stringent as in some other countries. This can allow low-quality or unsafe medical devices to enter the market. (4) Insufficient funding: The Chongqing medical device industry is underfunded, which can hinder its ability to invest in research and development, innovation, and quality control. Thus, the problems and difficulties facing the Chongqing medical device industry can have a significant impact on the city's ability to respond to public health incidents. For example, a shortage of high-quality medical devices can make it difficult to diagnose and treat patients during an outbreak. Additionally, low-quality medical devices can put patients at risk of infection and other complications (Chen, J., et al. 2022; Lu, Q., et al. 2022; Wang, Y., et al. 2022).

This study is a result of the urgent need to solve the shortcomings and difficulties present in the medical device industry, especially in light of emerging public health emergencies. Knowing the nuances of medical device operation, availability, and distribution becomes critical in light of the COVID-19 pandemic and other potential health emergencies. Chongqing, a populated urban hub in China, provides an appropriate context for this kind of research because of its diversified population and intricate healthcare system. The purpose of this study is to shed light on the particular challenges that healthcare providers and medical facilities encounter when trying to use medical devices in a public health emergency. This will help to develop focused approaches that will improve emergency preparedness and response in the area.

Research objective

1. To open up emergency inspection, inspection, and approval channels when medical supplies cannot meet urgent clinical needs and public needs, this will not only effectively secure the stable supply of medical devices, but also secure the safe and effective use of products.
2. To secure the avoidance explore the supervision of relevant medical device products and the problems and difficulties encountered in the supervision of various public health emergencies, to put forward relevant suggestions to avoid related problems or reduce the risks of medical device supervision.

Scope of the study

The scope of the research is the epidemic prevention medical devices in Chongqing in 2022. The research process starts from the quality inspection after the research and development of medical device enterprises, to the review and evaluation process after passing the inspection, to the listing after the review and approval, and finally to the market Sampling inspection of anti-epidemic medical devices for quality inspection is over. According to the statistics of the Chongqing Municipal Food and Drug Administration, in 2022, the city completed the emergency inspection and approval of 50 medical devices, playing an active role in effectively ensuring the timely diagnosis of novel coronavirus pneumonia during the epidemic and the clinical use of scarce medical and epidemic prevention materials.

Significance of the study

The technical specifications followed by the safety and reliability capabilities of medical devices are important technical support for regulating medical device regulation and promoting industrial development. The national standard management department, based on the actual development of the industry and regulatory work, continuously improves the medical device supervision and management system and carries out revisions to the medical device supervision system to continuously improve the medical device supervision system and enhance the technical support capacity for industrial development.

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Methodology

Samples and sampling

To strengthen the quality supervision of medical devices and ensure the safety of the people using them, by the general requirements of the "four most stringent" (the most stringent standards, the strict supervision, the most severe punishment, and the most serious accountability), according to the "Medical Devices According to the requirements of the "Administrative Measures for Quality Sampling Inspection" (National Drug Administration [2020] No. 9), combined with the actual situation of our city, the following sampling plan is formulated.

The overall batch plan for random inspection

Considering the time, economy, and energy costs of this research, and the requirement to screen samples covering multiple fields, regions, and links, the principle is to take up moderate resources, invest human and financial resources, and cover all districts of Chongqing with high accuracy. In 2022, the number of sampling inspections in the Chongqing market will be determined to be 26 batches, covering the links of operation.

2.1.2 Specific requirements for taking samples

In the operation link, Class II active medical device products of real estate enterprises in Chongqing are selected. Focus on extraction in the following order of priority:

1) Unqualified products in the market sampling inspection in 2021, such as the specific electromagnetic wave therapy device of Chongqing Xinfeng Medical Devices Co., Ltd. that failed in the market sampling inspection in 2021 (see Appendix A for details).

2) High-risk products that were not selected in the national sampling inspection in 2021, and that were not arranged for sampling inspection in this year's national sampling inspection. For example, the surgical shadowless lamp of Shenzhen Keman Medical Equipment Co., Ltd. was not picked up by the national sampling inspection (see Appendix A for details).

3) Epidemic prevention and control products. Varieties not included in the national sampling plan, such as forehead thermometers.

4) In 2021, the Chongqing Adverse Drug Reaction Monitoring Center disposed of products with more reports of suspicious medical device adverse events from registrants and filers in our city: specific electromagnetic wave therapeutic devices and infrared therapeutic devices.

5) Products registered with the self-inspect report.

6) Randomly select some newly registered and filed products in 2021, and medical device products commissioned by the registrant system (see Appendix A for details).

7) Products that are found to have major defects in the quality system of the enterprise during the inspection by the inspection bureau, and have hidden quality risks.

Note: If the same enterprise has many registered or filed products, in principle, one batch will be selected for each registration certificate. No more than 2 batches of active medical device products from the same enterprise (Try to extract the second-class products, and not the third-class products). Products that have been selected by the same company in the national sampling inspection in 2022 will no longer be selected.

Sampling statistics table

Table 1: List of Sample Types

No.	Sample type	Sampling link	Stock	Sampling batch	Sampling ratio	Application scenarios
5	Forehead thermometer	Operation	20	6	30.0%	monitor
6	Electronic thermometer		40	10	25.0%	monitor
7	Sphygmomanometer		20	10	50.0%	monitor
Total			**80**	**26**	**32.5%**	—

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Research instrument

The choice of inspection basis is the GB 9706 series of standards, among which the GB 9706.1 series of medical device field standards is one of the core standards for the general requirements of medical devices, providing strong technical support for the quality and safety supervision of medical device products.

The national standard "GB 9706.1-2007 Medical Electrical Equipment Part 1: General Safety Requirements" (hereinafter referred to as GB9706.1) was issued and implemented on July 1, 2008. The requirements of this safety standard are aimed at manufacturers and users of medical electrical equipment. GB 9706.1 stipulates in more detail the safety requirements applicable to various medical electrical equipment, including protection against electric shock hazards, mechanical hazards, excessive radiation hazards, flammable anesthetic gas ignition hazards, over-temperature and other hazards, and accurate working data. Eight aspects, including the prevention of sex and dangerous output, abnormal operation and fault state, and structural requirements (GB 9706.1—2007 Medical Electrical Equipment Part 1: General Safety Requirements [S]. Beijing: China Standard Press, 2007).

The safety inspection inspection involved in GB 9706.1 is a general type of inspection, that is, an inspection conducted with a sample that can represent the same type of item to be inspected. inspects that should only be made on those insulation, component, and construction features whose failure, under normal conditions or single fault conditions, would present a safety hazard (GB 9706.1—2007 Medical Electrical Equipment Part 1: General Safety Requirements [S]. Beijing: China Standard Press, 2007). Part of the inspection in the specific implementation process can be completed by the inspector without the use of tools. For example, the classification, appearance, structure, and circuit layout of medical electrical equipment in the standard mainly rely on inspection, experience judgment, and visual inspection. The other part can only be completed by the experimenter with the help of tools and instruments that meet certain technical parameters (The State Food and Drug Administration organizes. 2009).

GB 9706.1 gives clear requirements on the method and sequence of the inspection. However, the inspection items are covered in 58 chapters, 10 appendices, 16 tables, and 51 pictures (Li J., & Xu, Q. 2012). The relatively abstract text is boring, and the inspection tools required for most inspection items are not specified. GB9706.1, as the general safety requirements for medical electrical equipment, is the basis of the special safety requirements for medical electrical equipment. Therefore, for some medical devices designed to professional standards (such as "YY 0571 Medical Electrical Equipment Part 2: Special Requirements for Safety of Medical Electric Hospital Beds"), it is necessary to further refine the safety and performance requirements of medical devices through professional standards, and according to the professional Standard combined with GB 9706.1 for detection.

1) Forehead thermometer

Table 2: Inspection Items of forehead thermometer

No.	Inspection basis	Inspection items	Judgment principle
1	Technology requirement /GB/T 21417-2008	-Temperature display range -The maximum allowable difference within the specified -Resolution - Low voltage reminder function /4.3, 4.4.1, 4.6.1, 4.6.4	All qualified
2	GB 9706.1-2007	6.7, 16a), 19, 23, 49, 56.7, 56.8	All qualified

2) Electronic thermometer

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Table 3: Inspection Items of electronic thermometer

No.	Inspection basis	Inspection items	Judgment principle
1	Technology requirement / GB/T 21416-2008	-Display range -Resolution -Measuring the completed reminder function -Low temperature and over-temperature reminder function / 4.3.1, 4.3.2, 4.4.1, 4.4.2	All qualified
2	GB 9706.1-2007	6.7, 14, 16a), 19, 23, 24, 49, 56.7, 56.8	All qualified

3) Sphygmomanometer

Table 4: Inspection Items of sphygmomanometer

No.	Inspection basis	Inspection items	Judgment principle
1	YY 0670-2008	4.4.1.1, 4.5.1, 4.5.2, 4.5.3	All qualified
2	GB 9706.1-2007	6.7, 16a), 19, 23, 24.1, 24.3, 49, 56.7, 56.8	All qualified

Inspection items and comprehensive judgment principles

According to the shape, structure, electrical safety type, electric shock protection level, application scenarios, applicable standards, etc. Of different types of samples, the inspection items are as follows:

List of score ratios for each inspection item

According to the standard, each chapter has multiple subsections. For example, GB 9706.1 chapter 14 has 6 subsections, namely 14.1~14.6, and each subsection has multiple inspection items, such as 14.2a)~14.2c). If at least one item in a subsection is unqualified, then this subsection is judged as unqualified. For example, if items 14.2c) of subsection 14.2 in Chapter 14 are unqualified, then subsection 14.2 will be judged as unqualified, but it will not affect the judgment of subsections 14.1 and 14.3 to 14.6. However, items of Investigate due to the large impact of transportation and storage on inspection items, only the actual measurement situation is recorded, and no scoring and judgment are made, For example, subsections 6.1, 6.3, and 6.4.

Table 5: list of score proportions for each clause of various samples

NO.	Sampling link	Sample type	Inspection basis	Inspection item	Score ratios	Remark
5	Operation	Forehead thermometer	Technology requirement / GB/T 21417-2008	Temperature display range / 4.3	10%	—
				The maximum allowable difference within the specified / 4.4.1	15%	—
				Resolution /	10%	—

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NO.	Sampling link	Sample type	Inspection basis	Inspection item	Score ratios	Remark
				4.6.1		
				Low voltage reminder function / 4.6.4	10%	—
			GB 9706.1-2007	6.7	5%	—
				16a)	5%	—
				19	20%	—
				23	5%	—
				49	5%	—
				56.7	10%	—
				56.8	5%	—
6		Electronic thermometer	Technology requirement / GB/T 21416-2008	Display range / 4.3.1	10%	—
				Resolution / 4.3.2	10%	—
				Measuring completed reminder function / 4.4.1	10%	—
				Low-temperature and over-temperature reminder function / 4.4.2	10%	—
			GB 9706.1-2007	6.7	5%	—
				14	5%	—
				16a)	5%	—
				19	15%	—
				23	5%	—
				24	5%	—
				49	10%	—
				56.7	5%	—
				56.8	5%	—
7		Sphygmomanometer	YY 0670-2008	4.4.1.1	10%	—
				4.5.1	10%	—
				4.5.2	10%	—
				4.5.3	15%	—
			GB 9706.1-2007	6.7	5%	—
				16a)	5%	—
				19	15%	—
				23	5%	—
				24.1	5%	—
				24.3	5%	—
				49	5%	—
				56.7	5%	—

Table 5 continued

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NO.	Sampling link	Sample type	Inspection basis	Inspection item	Score ratios	Remark
				56.8	5%	—

Results

The research “Problems and Difficulties of Medical Devices in Chongqing in Response to Public Health Incidents in 2022”, found that

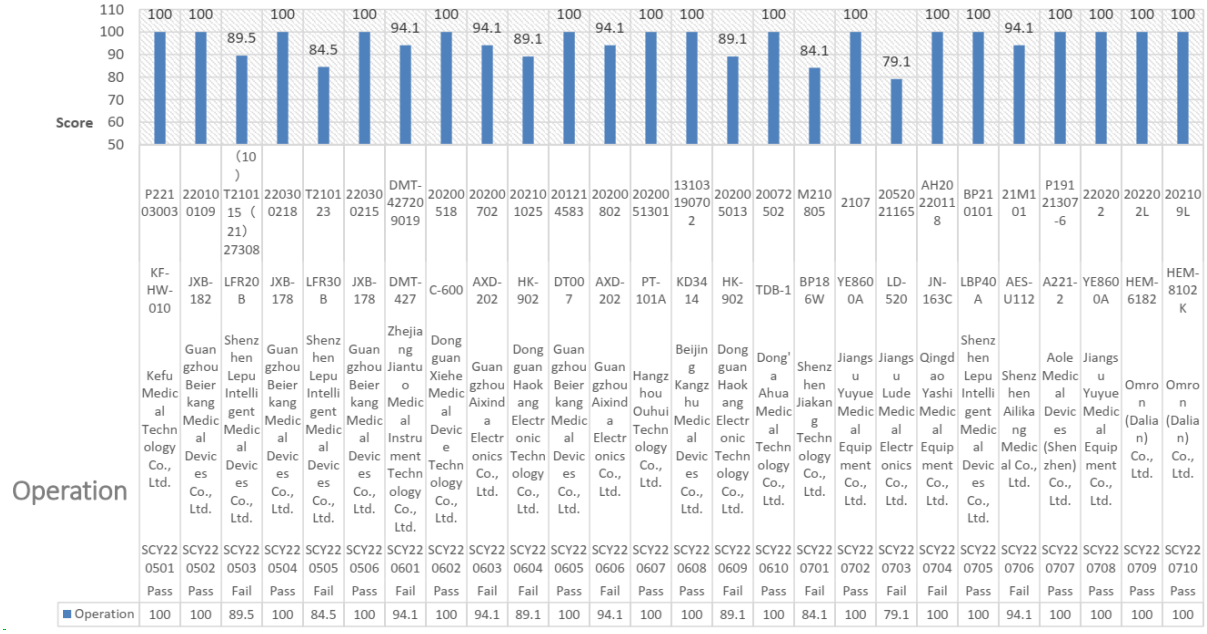

Figure 1: Histogram of sample scores in the operation link

Figure 1 is a histogram of sample scores based on the statistical table of samples in the operation link. This figure is the same as that in Figure 1, and it also has the final score, qualification status, and basic information of the samples, but compared with the samples in the manufacturing link in Figure 1, the number of samples in the operation link is more, the scoring situation is more, and the sample qualification rate is more complicated.

It can be seen from Figure 8 that as the number of samples increases and there are many manufacturers, even different models or different batches of the same type of products produced by the same manufacturer have different scores or inspection qualifications. For example, the report numbers are different. SCY220503 and SCY220505 are infrared forehead thermometers produced by Shenzhen Lepu Intelligent Medical Devices Co., Ltd. with the models "LFR20B" and "LFR30B" respectively. Because they are produced by the same manufacturer, these two models are listed in this In the random inspection, the unqualified performance indicators were also detected. Among them, the "LFR20B" model failed the inspection of the "temperature display range" item in the performance indicators, and the "LFR20B" model had the maximum allowable error within the specified temperature display range in the performance indicators. The "item" test failed because the weight of the item "maximum allowable error within the specified temperature display range" is greater than that of "temperature display range", so the "LFR30B" model sample has more points deducted than the "LFR20B" model sample. Although the "LFR20B" model sample scored more than the "LFR30B" model sample, it still did not reach the passing score for this category.

According to the statistics of the number of samples that have passed the inspection and failed the inspection, an intuitive total pass rate of samples in the manufacturing link and a pie chart of the pass rate of various products are drawn, as shown in Figures 9, 10, 11, and 12.

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Discussion

Legal and regulatory basis

The development of China's medical device industry started late, and the mechanism of medical device supervision is not perfect. China's medical device products will be strictly reviewed before they go on the market, but the review of medical device products after they go on the market is relatively loose. At this stage, China's medical device supervision model and supervision system are developed from the experience and lessons learned from foreign supervision, and combined with China's national conditions and the status quo of the medical device industry (Yi, Y., et al., 2014). However, at this stage, China's medical device regulatory regulations have not yet risen to the legal level. The content of the regulatory regulations is rough and lacks timeliness. The overall regulatory system is not perfect and the infrastructure is weak.

Regulatory Review Standards and Safety Hazards

As we all know, medical device products can be divided into Class I, Class II, and Class III medical devices according to the degree of risk. Class I medical devices have a low-risk level. Generally, they only need to go to the local prefecture-level food and drug administration for filing, such as hemostatic patches, absorbent cotton balls, scalpels, etc. The risk level of Class II medical devices is higher than that of Class I medical devices, and they need to obtain a registration certificate after approval by the provincial Food and Drug Administration before they can be marketed, such: thermometers, blood pressure monitors, real-time fluorescence immunoassay analyzers, etc. The three types of medical devices have the highest risk, and the products must be approved by the State Food and Drug Administration before they can obtain a registration certificate. Such as implantable cardiac pacemakers, hollow fiber hemodialysis filters, etc. Medical device products with different risk levels need to be approved by different levels of review departments to obtain registration certificates. However, the system also has problems such as inconsistent review standards in different regions, which to some extent also creates hidden dangers for the safety of products after they go on the market. The main reason for this phenomenon is that the professional competence of reviewers in various regions is uneven, and review agencies in different regions have inconsistent review rigor for the same product.

Lack of professional supervision team

The country's medical device testing resources are scarce, and the testing capabilities of medical device testing institutions are weak. From the 22 sub-categories in the latest version of the medical device classification catalog, it can be seen that the product types covered in it have been refined and expanded to 206 first-class and 1157 second-class products, and 6609 typical products are given as examples. It can be seen that the current medical device products cover a wide range and variety. In addition, with the development of technologies such as biomaterials, 5G, 3D printing, information engineering, and big data in China in recent years, a series of innovative medical devices products such as artificial intelligence and implants have emerged (Li, A., et al., 2021). This further illustrates the greater coverage and complexity of current medical device products. However, the rapid development of innovative medical products also places extremely high demands on the professionalism of medical device regulators. At this stage, there has been a trend of mismatch between the testing capabilities of China's medical device testing institutions and the testing needs of complex medical device products. The main manifestations are the lack of employees in the testing industry, the lack of professional knowledge of inspectors the lack of work experience and inspection ability, and the instability and serious loss of testing personnel in institutions. These problems make it impossible for the regulatory authorities to carry out more diversified professional supervision of the industry, leading to certain difficulties in the supervision of medical devices (U.S. Department of Health and Human Services. 2020)

Problems of some medical device enterprises

Medical devices have dual attributes of public welfare and profit, which can bring good economic benefits while preventing and treating diseases. Medical devices are closely related to the health and safety of the public, but at this stage, some heads of medical device companies still have the wrong idea of "emphasizing economic interests and ignoring public safety". As of 2021, there are 28,954 medical device manufacturers in the medical device market, and the competition in the entire industry is very

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fierce. To stand out in the fierce competition, some business executives are not strict enough in the production process of medical devices and use inferior production materials to reduce production costs and increase product revenue. As everyone knows, such behavior not only brings potential health and safety risks to the public but may even cause serious casualties.

Product inspection standard update and safety judgment scale

The country implements classified management of medical devices, and medical device products with different risk levels need to be filed or registered with different review agencies before they can enter the market. According to the "Standardization Law of the People's Republic of China", the entire standard system of our country can be divided into national standards, industry standards, enterprise standards, and local standards (Xu, W., et al., 2010). Due to the complexity of medical device products, there are no specific inspection standards for the testing of some medical devices, and enterprises need to formulate relevant standards by themselves. But at the same time, the testing standards drawn up by enterprises may not meet the requirements of product filing and registration, and the testing conducted by different companies according to the same testing standards may also have different safety index judgment standards. It can be seen that the current standards in China cannot fully meet the development needs of medical device products, and the national standards and industry standards cannot be kept up to date with international standards, resulting in the lack of corresponding testing standards for existing innovative medical products, making it difficult to form a unified and complete and safety standards.

Degree of public participation in medical device regulation

Medical devices are widely used in hospitals, families, communities, clinics, nursing homes, and other places, and can be seen everywhere in the daily life of the public. The supervision of the quality of medical equipment products requires the joint participation of the supervision department and the general public. The participation of the public in supervision can reduce the flow of inferior medical devices into the market, and to a certain extent, it can prevent the regulatory authorities from falling into the dilemma of independent supervision (Li, A., 2022). But at this stage, the basic medical knowledge of the general public in our country is weak, and the awareness of reporting adverse events is not strong. Some people think that the supervision of medical devices is not relevant to them. The awareness of public participation is not strong, and the overall participation level is low.

Recommendation

Improving the legal status of medical device regulatory legislation

The supervision of medical devices needs to cooperate with high-level laws and regulations as the cornerstone. At present, China's medical device supervision and management regulations are mainly promulgated by the State Council. The legal effect of the regulations is lower than that of the constitution and general laws. It is a normative document belonging to administrative regulations and lacks a certain degree of binding force. In the future, it is necessary to refer to the regulatory practices of food and drug safety to speed up the legal construction of medical device supervision, so that it has the same legal status as drug and food supervision. At the same time, in the legislative process, it is necessary to pay attention to clarifying the legal responsibilities of medical device regulatory bodies at all levels, to provide a legal basis for scientifically controlling regulatory risks.

Strengthen the responsibility awareness of the person in charge of the main body of medical devices

If the supervision of medical devices only relies on the supervision of the government and the public, it cannot guarantee the product quality and safety of medical devices. As the first person in charge of medical devices, the personnel of the medical device company needs to improve the self-discipline awareness of the person in charge and enhance the sense of responsibility and mission of the person in charge. Government departments and industry departments need to strengthen the training of responsible persons to help them understand laws and regulations, be familiar with the registration process, and be familiar with the quality management system of medical devices. At the same time, government agencies should also strengthen incentives, guidance, persuasion, warnings and warnings for the responsible persons, and improve the ideological awareness of the responsible persons.

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Establish a high-quality professional supervision team

The quality of supervisory work is closely related to the professional ability of supervisors. To match the supervisory body and supervisory force in the supervisory work, it is necessary to regularly carry out professional knowledge and professional skills training for supervisory practitioners. By improving the professional level of supervisory practitioners, to ensure the quality of supervision. At the same time, the state should encourage colleges and universities to open majors related to medical devices to provide relevant talents for medical device supervision. Finally, in response to the phenomenon of medical device brain drain, it is necessary to improve the salaries and benefits of employees and expand promotion channels, to mobilize the enthusiasm of employees. Only in this way can we ensure that the regulatory force matches the scale of product development.

Actively improve the medical supervision information platform

The information platform can improve regulatory efficiency by integrating medical product filing and registration information, random inspection information, adverse event monitoring information, supervision and inspection, and other information (Zou, J., et al., 2016). The construction of an information platform can help regulatory authorities across the country share information and grasp the regulatory situation in the first place, thereby improving regulatory efficiency. Evaluation centers in various regions need to speed up the improvement of the review information platform and use big data, artificial intelligence, and other technologies in the review process to quickly and accurately identify key review points and product innovation points. At the same time, it is also important to strengthen information technology education for review personnel, realize the full coverage of "Internet +" supervision, expand the sharing of national supervision information, open platform supervision communication channels, and encourage the public to actively participate in medical supervision.

Strengthen social supervision and establish a "blacklist" of medical device companies

Since the outbreak of the novel coronavirus pneumonia, a large number of cross-border medical device companies have poured into the medical device market, but all kinds of medical device companies entering the market are mixed. At the same time, with the rapid development of webcasting platforms, sales channels in the medical industry have become more diverse, and the backgrounds of participants have become more complex. To ensure the standardized operation of the medical market, we can start from the following aspects: First, improve the electronic traceability supervision system for the products of medical device companies, and strengthen the punishment for selling unqualified medical device products on the Internet and live broadcast platforms. The second is to set up several special reporting lines to open an effective and convenient complaint path for the public, to facilitate the public report of unqualified medical device products. The third is to call on consumer associations, industry associations, and other forces to participate in the supervision of medical devices; strengthen the publicity and interpretation of medical device-related policies, so that more market players can fully understand government policies, and the market and the government will jointly participate in the supervision of medical devices. The fourth is to increase the exposure of unqualified medical device product companies, and include medical device companies that have adverse events on the "blacklist"; these companies will be the key observation objects, and the listing of their follow-up products will also be strictly reviewed, and additional Large-scale supervision and spot checks and spot checks. At the same time, regulatory authorities at all levels actively promote the information disclosure of "blacklisted" companies, realize information sharing, and safeguard the rights and interests of medical device product entities.

Improve and standardize inspection standards and improve standard quality

In recent years, adverse events of medical devices in China have occurred frequently, and the same product lacks a unified evaluation standard, which affects the safety and health of public devices (Mu, R., et al., 2011). With the rapid development of medical device products, the national medical device standard management department should attach importance to standard formulation and speed up the revision of standards; in the process of standard formulation, medical device companies, scientific research institutions, and group members should be actively involved; During the process, the revision status should also be made public and announced to the public. At the same time, it is necessary to carry out regular training on testing standards to deepen the understanding of standards by inspectors,

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reviewers, and internal personnel of the enterprise, and promote the implementation of various standards. Finally, the standard query system needs to be further improved to facilitate practitioners to obtain standard update information in the first place.

Encourage the public to actively participate in medical devices and improve the quality of medical device products

The enthusiasm of the public to participate in the supervision of medical devices is directly related to the coverage and effectiveness of supervision. To better promote the participation of the public in the supervision of medical devices, the medical department can carry out online public welfare training, regularly conduct medical device knowledge lectures in the community, and popularize science and technology for daily medical devices products such as blood pressure monitors, blood glucose and uric acid meters, and thermometers. Calibration maintenance helps the public better use medical device products. Government agencies should open a hotline for reporting adverse events, and respond promptly and quickly to adverse events reported by the public. Incentive measures can also be set up to give appropriate rewards for major adverse events reported by customers. Only by introducing public regulatory forces and establishing a reporting and feedback mechanism for adverse events can the regulatory authorities understand the quality problems of medical products circulating on the market, recall defective products as soon as possible, and prevent inferior products from continuing to flow into the market.

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