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Review Article

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The Enlightenment of the Management of EU Notified Bodies to China's Introduction of Third-Party Institutions for Medical Device Supervision

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Abstract

Objective: By introducing the pilot situation of post-market supervision of medical devices purchased by third-party institutions in Jiangsu Province, China, the problems exposed by them were analyzed. At the same time, it draws on relevant advanced experience in the management of EU notified bodies to provide suggestions for optimizing China's follow-up practices and promoting social co-governance supervision.

Method: Conduct on-the-spot investigations in Jiangsu Provincial Food and Drug Administration, China, conduct interviews with regulators on the progress of the project, and conduct in-depth communication. A large number of inquiries about the relevant research literature of the EU notified body and the laws and regulations promulgated by the EU, and systematic analysis.

Results: In the introduction of third-party agencies to assist post-market supervision of medical devices, the Chinese government still has problems such as lack of relevant laws and regulations, imperfect access mechanisms for third-party agencies, imperfect supervision mechanisms, and backward regulatory informatization construction.

Conclusion: Introducing third-party agencies to assist in the supervision of medical devices can effectively ease the pressure on supervision and supplement supervision resources. It is suggested that the Chinese government learn from the management experience of the EU notified bodies, improve the regulatory legal system, introduce relevant regulations, improve the access mechanism of third-party institutions, improve the supervision mechanism, strengthen the construction of supervision informatization, and build a unified supervision platform.

Keywords: Third Party; Medical Devices; Post-Marketing Supervision; EU notified body, Medical Device Supervision, informatization

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1. Introduction

With the rapid development of China's medical device industry, problems such as heavy regulatory pressure and lack of regulatory resources have become increasingly prominent. Internationally, third-party institutions play an important role in the field of medical device supervision, such as the EU's notified body system, the US third-party 510k audit program, and the single medical device audit program implemented by the International Medical Device Regulators Forum. In 2013, the General Office of the State Council of China issued the "Guiding Opinions on the Government's Purchase of Services from Social Forces", (1) which pointed out that "in basic public services such as medical and health care, the government should gradually increase the intensity of the government's purchase of services from social forces, and promote the government to purchase services from social forces, transformation of functions, integration and utilization of social resources". In this context, the Jiangsu Medical Product Administration actively explored, through government bidding and procurement, entrusting a third-party agency to assist in undertaking the on-site inspection of the quality management system of some medical device manufacturers. This paper mainly studies the problems that occurred during the pilot implementation of this project in Jiangsu Province, and combined with the relevant experience of the management of the EU notified body, it puts forward suggestions for improving the relevant work in my country in the future.

2. Project Pilot Situation in Jiangsu Province

The Jiangsu Medical Product Administration is the competent authority mainly responsible for the relevant licensing, registration and post-marketing supervision and management of drugs, medical devices and cosmetics in Jiangsu Province, China.

2.1 Pilot content

In order to ease regulatory pressure, speed up the transformation of government functions, and promote social co-governance, the Jiangsu Medical Product Administration officially launched a six-month pilot project of third-party purchase services in May 2021, and selected three third-party purchase service projects through bidding procurement. Three-party agencies conducted an evaluation of the effective operation of the post-market quality management system for 50 high-risk medical device manufacturers in the province.

2.2Third-party agency workflow

The inspection process of the third-party agency consists of three steps, the first meeting, the on-site inspection and the closing meeting. The first meeting mainly introduced the members of the inspection team, announced the inspection discipline and explained the inspection basis, and introduced the operation of the quality management system of the inspected enterprise. Secondly, inspectors from third-party institutions conduct on-site inspections of the quality management system of the inspected enterprises. After the inspection, the final meeting will be held again to notify the inspected enterprise of the inspection results, and the enterprise will confirm the inspection conclusion. If the enterprise has any objection, it can make a statement and defense on the spot. If necessary, the inspection team can further confirm the situation and make a record. Third-party institutions conduct inspections in accordance with the "Good Manufacturing Practice for Medical Devices" and its annexes, inspection guidelines and other documents, focusing on high-risk, quality complaints or adverse events, unqualified random inspections, and complex products. The inspection methods mainly include on-site inspection, inquiry, document inspection, photographing and recording, etc. After the inspection, the on-site inspection record form and inspection report need to be filled out.

2.3 Judgment of inspection results

After the inspection, the inspection team of the third-party agency needs to submit an inspection report and all other relevant documents. The content of the documents should at least include the basic information of the inspected enterprise and products, the inspection process description, the problems and the basis and suggestions for handling, etc. And make a comprehensive analysis and evaluation of the systematicness, authenticity, effectiveness and standardization of the enterprise quality management system. The Jiangsu Medical Product Administration will re-check the inspection report, communicate with the project leader to reconfirm the inspection situation, and conduct risk consultations to evaluate the third-party work. The decision of the final inspection is made by the supervisory authority. In addition, the Jiangsu Medical Product Administration evaluates the work of the third party by reviewing the inspection report submitted by the third party, and the "On-site Inspection and Evaluation Work Enterprise Feedback Form of the Third Party Agency" filled out by the inspected enterprise. The content of the feedback sheet mainly includes the evaluation of the business capability, knowledge level, integrity and self-discipline and inspection effect of the third-party organization.

3. Problem analysis

In this pilot, although third-party institutions have achieved certain results in alleviating regulatory pressure and supplementing regulatory resources, there are still many problems that need to be improved.

3.1 Lack of relevant laws and regulations

At present, China has not promulgated relevant laws and regulations on the management of third-party institutions. Third-party evaluation institutions are often included in the category of private non-enterprise units, and their unique identity in the entire social organization system has not been reflected. (2) The basic conditions such as status, ability and qualification, responsibilities and obligations are clearly stipulated, resulting in the lack of legal identity. The third-party agency stated that its legal status was often questioned when it went to the inspected enterprise for inspection, and a series of explanations and explanations were required to the inspected enterprise, which greatly reduced the work efficiency.

3.2 Lack of strict third-party agency access mechanism

Second, third-party agencies lack strict access procedures. On the one hand, qualification requirements are too general. The government's qualification requirements for third-party institutions in the pilot program only emphasized the legal personality of the institution and the nature of its work, and the confidentiality and impartiality of the work process. Such details are not uniformly stipulated, which will easily lead to uneven inspection quality among third-party agencies and large differences in inspection results. On the other hand, after the government procures third-party institutions through bidding, it does not conduct self-assessment on the third-party institutions. The late start of government procurement in China, the lack of professional talents in agencies, and the lack of effective supervision of the bidding agency process may cause that the selection results don’t comply with the present requirements. (3)

3.3 Insufficient enthusiasm of third-party agencies

At present, there are only a small number of third-party institutions engaged in medical device certification in China, and the market size is narrow and there are very few well-known ones. In this pilot tender, only three third-party institutions signed up, which led to the lack of choice for the government and the inability to accurately compare and screen. And most of these third-party institutions are engaged in foreign certification activities, and their internal inspectors are very good at foreign medical device certification systems and related

laws and regulations, and they are very familiar with the domestic "Quality Management Practice for Medical Devices" and its appendices and inspection guidelines. Due to lack of familiarity and understanding of laws and regulations, inspection thinking is quite different from that of medical device supervisors in Jiangsu Province.

3.4 Lack of strict monitoring mechanism

As a commercial organization, third-party organizations, on the one hand, have high employee turnover, and there is a risk of leaking the commercial secrets of the companies under inspection; on the other hand, they are highly profit-seeking. In addition to cooperating with government regulators, they also engage in many other related businesses, such as EU CE certification, regulatory training, etc., there is a risk of using the inspection identity to develop customers, and it has an interest relationship with the inspected enterprise, and the impartiality of the inspection results cannot be guaranteed, so it must be strictly supervised. However, the Jiangsu Medical Product Administration has not yet established a strict supervision mechanism for third-party institutions, and only provides feedback through some documents, which cannot guarantee the authenticity of the inspection results.

3.5 Insufficient construction of regulatory information

Most of the regulatory information in Jiangsu Province is an isolated island of information, which has not been integrated and effectively utilized. The Jiangsu Medical Product Administration cannot directly access and consult the regulatory information of the inspected medical device companies in the province. Before the inspection, it needs to continuously feedback information with the liaisons of the municipal drug administrations, which is inefficient.

The introduction of third-party institutions in Jiangsu Province to conduct post-market supervision of medical devices is in the exploratory stage, and the implementation process has exposed many problems. The notified body system adopted by the EU has been tested in practice for many years and has been widely recognized internationally. Therefore, studying the management methods of EU notified bodies has certain reference significance for Jiangsu Province.

4. EU Notified Bodies

The EU Notified Body is a social third-party institution that has been officially recognized by the EU member states and qualified after the EU's unified official announcement. (4) It is not only responsible for medical device product certification, but also responsible for post-market supervision, and has certain approval and supervision powers. For medium and high-risk devices, the CE mark is provided by notified body. (5) In 2017, the Official Journal of the European Union officially released the EU Medical Device Regulation (Regulation (EU) 2017/745, referred to as MDR), which was implemented on May 26, 2021. (6) There are strict regulations on the qualifications, evaluation process, work requirements and supervision of notified bodies in the regulations. The legal status of notified bodies is clear, there is no questioning problem, and the social recognition is very high. At the same time, the national competent authority will clarify the scope of appointment of conformity assessment activities of all notified bodies, the types of devices authorized for assessment, and the unique effective identification number assigned to them. This information will be included in the electronic database developed and managed by the European Commission by the member state where the notified body is located, and notified to other member states, and the activities of the notified body will be continuously monitored.

4.1 Qualification requirements for notified bodies

4.1.1 Total requirements

The EU has strict qualification requirements for notified bodies, including the general requirements of the organization and the qualification requirements of personnel. The organization generally emphasizes independence, impartiality and confidentiality. For independence, the notified body must be independent from the equipment manufacturer and any institution or organization that has an interest in the equipment. For impartiality, notified bodies are required to implement structures and procedures that safeguard and promote impartiality, and identify, investigate and resolve situations that may give rise to conflicts of interest. (7) With regard to confidentiality, unless disclosure is required by law, all relevant personnel must keep all information involved in the conduct of conformity assessment activities confidential. In addition, the notified body also needs to establish a quality management system suitable for conformity assessment activities, strictly set personnel qualification standards, document personnel qualifications, training and authorization; at the same time, establish a supervision mechanism and an experience exchange mechanism.

4.1.2 Personnel qualification requirements

The EU medical device regulations strictly control personnel qualifications, requiring notified bodies to have personnel with corresponding qualifications, the science and technology, equipment, facilities and evaluation capabilities involved in the implementation of their designated conformity assessment activities. The key personnel responsible for the review in the notified body mainly include: product reviewer, quality system reviewer and final reviewer. The EU medical device regulations have requirements on the education, experience, knowledge and other aspects of these personnel as shown in Table 1.

4.2 Notified Body Evaluation Mechanism

4.2.1 Evaluation subject

As an important social force in EU medical device review and supervision, notified bodies participate in the review activities as an important line of defense to check product safety and effectiveness, and are closely related to public health. To this end, the EU has established a complete evaluation mechanism for notified bodies. The assessment of notified bodies involves three assessment bodies, namely the national competent authority responsible for notified bodies, the European

Commission and the Medical Device Coordination Group (MDGG). The coordination group is composed of members designated by member states, mainly to facilitate information exchange and coordinate assessments, and to provide various support to competent authorities.

Table 1. Personnel qualification requirements

Personnel category	Education background	Experience	Related information	Other
product reviewer	College degree or above in medicine, pharmacy or other related majors or equivalent qualifications	Four years of professional experience in the medical industry and two years of evaluation experience in the industry	Device legal knowledge, relevant harmonized standards, general specifications and guidance documents, risk management and performance assessment knowledge	Assess device-related knowledge, authority to perform assessments; develop records and reports
Quality System reviewer	College degree or above in medicine, pharmacy or other related majors or equivalent qualifications	Four years of professional experience in the medical industry and two years of evaluation experience in the industry	Device legislation and related harmonized standards, general norms, risk management, device standards, quality management system guidance documents	Knowledge and experience of the conformity assessment process, authority to perform assessments; receive training in auditing techniques; develop records and reports
final reviewer	Qualifications, experience and expertise related to device conformity assessment	Medical device technology foundation, including conformity assessment and certification, device design and manufacturing experience ;	Device Laws and Related Guidance Documents	Create records and reports

4.2.2 Evaluation process

The assessment of the notified body is divided into three steps, initial document review, document review and on-site assessment. The specific process is shown in Figure 1. After the on-site assessment, the competent authority of the notified body will list the non-conformance items to the applicant body, and the applicant body should submit a corrective and preventive action plan within the specified time limit. has been properly addressed and the plan and comments are forwarded to the Joint Evaluation Team. Finally, the competent authority of the notified body is responsible for formulating the final evaluation report and submits it to the committee, the medical device coordination group and the joint assessment group. These three can make relevant recommendations to the competent authority of the notified body. The competent authority of the notified body will make a decision on the notified body. The final evaluation is completed with due consideration of these recommendations and the relevant recommendations of the Comprehensive Committee, the MDGG and the Joint Evaluation Group. Such multi-subject collaboration, clear division of labor, and rigorous evaluation methods are conducive to ensuring the fairness and impartiality of evaluation results, and selecting targets that meet the requirements.

After the assessment, the European Commission will publish the list of notified bodies qualified for the assessment on the NANDO website, which will provide instructions for each notified body to be responsible for the conformity assessment of medical devices.(8) Device manufacturers can browse the website, click on the legislation, select the relevant directives or regulations, and then find the designated notified body according to the scope, and freely choose a notified body for medical device conformity assessment.

4.3 Regulation of Notified Bodies

In recent years, the frequent occurrence of adverse events in the EU reflects that the notified bodies are still insufficient in supervision. Therefore, the new EU regulations have stricter regulations on the supervision of notified bodies. (9) The supervision of the notified bodies in the EU is in charge of the competent authority of the notified body. The supervision methods mainly include annual review, re-assessment and technical review. The specific content is shown in Table 2. Any findings that the notified body is found not to comply with regulatory requirements shall be recorded and archived, and its timely remedial and preventive actions shall be monitored. In addition, Notified Bodies are required to submit an annual regulatory or review plan to the Medical Device Coordination Group and Committee. Once it no longer meets the requirements, it will be removed from the list of notified bodies to play a supervisory role.

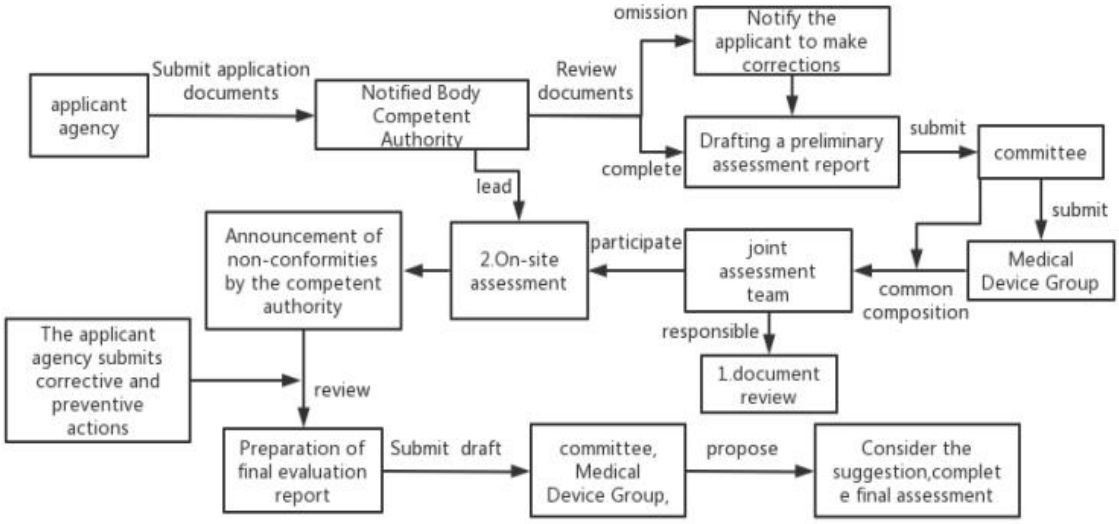

Figure 1. Notified Body Assessment Procedure

Table 2. Notified body supervision method

Supervision method	Frequency	Implementation subject	Implementation form
Annual review	at least once a year	national authorities	On-site audit, unannounced visit, and cause-based verification
Reassessment	every Quadrennial	Designated Joint Review Panel	Full re-review of documents, on-site assessment
Technical review	unspecified time	national authorities	notified body evaluation report for manufacturer's technical file, performance evaluation

4.4 Supervision information construction

In addition, in order to increase the public's understanding of medical devices, certification bodies and clinical research, realize the traceability of medical devices, and enhance the exchange of information among various competent authorities, the European Commission has established the European Medical Device Database (Eudamed), which includes six major Modules, operator registration system, UDI and medical device registration system, notified body and certification system, clinical investigation and performance study system, vigilance and post-market surveillance system and market surveillance system. (10) The EU Commission will perform trending and signal detection based on the data in Eudamed. So far, the first three modules are available, and the last three modules are still under development. The integration of major information is conducive to promoting the circulation and utilization of information, and better providing information to the public and medical personnel. My country should also actively explore and try in the development of medical device information system.

To sum up, the EU has a series of complete management systems for notified bodies, from strict qualification requirements, evaluation mechanisms, supervision mechanisms and support of supervision information systems, all of which are worthy of reference for China.

5. Reflections and enlightenment

5.1 Improve the regulatory legal system

The EU medical device regulatory document clarifies the legal status of the notified body, and makes detailed provisions on its qualifications, work requirements and responsibilities and obligations, which provides institutional support for the work of the notified body, and its legal status has been recognized by the society member's approval. (11) It is suggested that China improve relevant laws and regulations, issue special laws and regulations to manage third-party institutions as soon as possible, or incorporate the management of third-party institutions into existing laws and regulations, such as the Regulations on the Supervision and Administration of Medical Devices, to determine the legal identity of third-party institutions At the same time, it restricts the behavior of third-party organizations, such as formulating punitive measures for leaking user information or taking bribes and corruption, so as to enhance the legitimacy and fairness of inspections. In the current legal blank period, it may be possible to consider allowing the government to provide red-headed documents to third-party agencies for inspection to reduce inspection obstacles and improve the rules and regulations for government procurement of services, refine specific implementation requirements and procedures, and provide institutionalized guidance.

5.2 Introduce relevant incentive policies

In addition, the government should introduce relevant encouraging policies, such as tax incentives, financial subsidies, bonus support, etc., to cultivate my country's third-party institution market, promote the development and construction of China's third-party institutions, and lay the foundation for further improving the social co-governance supervision pattern in the future. At the same time, relevant government departments should strengthen publicity and guidance and do a good job in policy interpretation, create a good public opinion environment, and attract more third-party institutions to actively participate in social co-governance.

5.3 Improve the access mechanism of third-party institutions

The quality of third-party institutions directly affects the implementation effect of the project, so the government should establish a strict access mechanism for them. On the one hand, strictly set qualification requirements. First of all, it is recommended to make requirements from the aspects of the independence of the organization, the impartiality and confidentiality of the inspection process, and the quality management system suitable for the inspection requirements. Secondly, for inspectors, especially key personnel, strict requirements should be set in terms of academic background, relevant work experience and years in the medical device industry, medical device-related professional knowledge and knowledge of laws and regulations, device evaluation capabilities, and the training and education they have received. On the other hand, improve the evaluation mechanism. The evaluation subject shall be clearly defined, and the various departments shall have a clear division of labor to cooperate and supervise together. In terms of the evaluation process, it can be divided into three steps: initial document review, document review and on-site assessment. The competent department can be responsible for conducting a preliminary formal review of the applicant's documents and writing a preliminary assessment report; secondly, the medical device coordination group conducts a review of the documents; finally, the medical device coordination group and the competent department jointly conduct on-site audits of third-party institutions, and jointly negotiate, determine the final assessment results.

5.4 Establish strict supervision mechanism

The government should implement the supervision mechanism for third-party institutions. First, the main body of supervision should be defined, and the supervision responsibility should be assigned to specific departments. Secondly, each third-party institution should be assigned a unique number and incorporated into the information system to strengthen monitoring and information traceability. Secondly, the third-party agency can be supervised by means of irregular on-site evaluation and document inspection, such as inspection reports, records, and evaluation documents, to ensure that the third-party agency continues to maintain the inspection capability that meets the requirements. When it does not meet the requirements, its inspection qualification should be revoked and it will not be included in the next year's purchase plan. Finally, it is necessary to establish a complaint and reporting mechanism and improve the information disclosure system, publish the inspection results, improve the transparency of inspections, accept social supervision, and use the inspection feedback from the society and enterprises on third-party institutions as part of the basis for inspecting third-party institutions. (12)

5.5 Strengthen personnel training

In addition, inspectors play an important role in the post-market safety supervision of medical devices and undertake important inspection tasks. Their professional quality and law enforcement ability directly affect the level of life and health protection of the Chinese people. It is recommended that the regulatory authorities regulate the process and inspection reports of third-party institutions for quality management system inspections, and continue to strengthen the study and education of inspectors. (13) On the one hand, through regular regulatory training and experience exchange meetings, inspectors can learn and get in touch with foreign advanced regulatory concepts and experience, improve their ability to detect and deal with defects, and at the same time strengthen third-party agencies' understanding of my country's medical device laws and regulations , to understand the current situation of medical device manufacturers in Jiangsu Province and the focus of domestic medical device supervision and inspection, which is conducive to promoting the two sides to jointly discuss the similarities and differences of domestic and foreign supervision concepts, and to explore the supervision methods suitable for the actual situation of medical device enterprises in Jiangsu Province. The other third-party institution needs to strengthen internal training. It should clarify the initial and continuous training plan required by each individual, and conduct regular professional training and regulatory training and assessment to ensure that the inspectors continue to maintain inspection qualifications and professional capabilities, and can efficiently complete the Jiangsu Province Pharmaceuticals. Inspection tasks are arranged by the supervisory authority.

5.6 Strengthen the construction of supervision informatization

Medical device informatization construction is an important policy support to comprehensively strengthen the supervision of medical devices. Through the integration of resources and interconnection, various risk prevention and control links in the whole life cycle supervision chain of medical devices can be connected in series, and national and local regulatory authorities at all levels can be connected. Join with technical departments to form a three-dimensional medical device regulatory information framework. (14) The establishment of EU's Eudamed database improves information transparency, strengthens post-market supervision and information flow and utilization. China should also actively try to develop a unified medical device supervision information platform, and integrate the medical device registration electronic system, UDI database, certificate electronic system, clinical research

system, vigilance and post-marketing supervision system, etc. The dynamic supervision data chain of the whole process after the event, so that the provincial and municipal drug supervision and management departments can rely on this platform to share data, strengthen the coordination of information reception and supervision, form a coordinated supervision mechanism that runs smoothly, and promote smart and precise supervision of medical devices and risk regulation.

6. Conclusion

The introduction of third-party institutions to conduct post-market supervision of medical devices is of great significance for supplementing supervision forces, innovating supervision methods, and promoting social co-governance. However, there are still many problems in the implementation of this model. To fully implement it, multiple social entities are needed and they work together to advance and explore a more effective way of connecting third-party agencies and the government to jointly supervise.

Author Contribution

Qingqing Hou have made substantial contributions to the conception and design of this work.Yiming Xu and Dawei Zhang have taken part in revising work critically for important intellectual content. Yi Liang has revised work and approved the final version to be published.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article

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