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China: Trends and Developments

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Trends and Developments

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Han Kun Law Offices

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Regulating Medical Devices in China in 2024

In the year 2023–2024, China made continuous updates to its regulatory policies regarding medical devices, with active contributions from the National Medical Products Administration (NMPA), the National Health Commission (NHC), the State Administration for Market Regulation (SAMR), and the Ministry of Science and Technology (MOST). The advancements in regulatory policies encompass the entire life cycle of medical device products, from research and development, registration, manufacturing, and commercialisation, to post-market vigilance.

General

Legislation of the Medical Device Administrative Law

China continues working on the pre-legislative study of the Medical Device Administrative Law in 2024.

The Medical Device Administrative Law was included in the legislative plan of the 14th National People's Congress (NPC) Standing Committee in 2023. On 28 August 2024, NMPA officially released the Medical Device Administrative Law (Draft for Comment) for public comments. Once finalized in future, it will become the highest level of law in the regulatory regime of medical devices.

Since the Medical Device Administrative Law was first included in the national legislative plan, the authorities have been continuously engaging in legislative research and investigation. Multiple medical device enterprises have been visited, and various seminars have been held to have in-depth discussions on the further improvement of the legal regime for medical device regulation and the promotion of a high-quality medical device industry.

Foreign investment

On 8 September 2024, the Ministry of Commerce, together with NHC and NMPA, publicly issued the Notice on Carrying Out Pilot Programs to Expand Opening-Up in the Healthcare Sector, announcing that qualified foreign-invested enterprises are permitted to engage in the development and application of human stem cells, gene diagnostic and therapy technologies for product registration and manufacturing in four free trade zones in Beijing, Shanghai, Guangdong, and Hainan. This marks another significant step forward for China's healthcare industry (including the diagnostic medical device industry) on the path of open development."

Research and development

Clinical trials

In order to strengthen the management of medical device clinical trial sites, NMPA issued the Measures for the Supervision and Inspection of Medical Device Clinical Trial Sites (Trial) on 14 June 2024, which will become officially effective on 1 October 2024.

This regulation applies to the inspections carried out by regulatory authorities against medical device clinical trial sites. The key points of inspections cover various aspects such as the sites' qualifications, management of filings, and management of clinical trial operation.

According to this regulation, regulatory authorities may increase the frequency of inspections or specify them as priorities of inspections if the following situations occur:

- if authenticity issues are found in clinical trial project inspections within the past two years;
- if the site has been determined as non-compliant in clinical trial site inspections within the past two years;

- if the quality of clinical trials may be impacted due to reasons such as the principal investigator is undertaking multiple clinical trial projects at a time, has insufficient management capabilities or has an inadequate number of research personnel;
- if complaints, reports, or other clues indicate potential quality and safety risks; and
- other indications of the site's quality management risks, such as not conducting clinical trials for over two years.

For clinical trial sites determined as non-compliant in the inspections, the regulatory authorities shall require them to suspend new clinical trials until rectifications are completed within six months. If rectifications are not completed within such period, the filing of such clinical trial site, which is the fundamental requirement for an institution to conduct medical device clinical trials, will be cancelled.

The regulatory authorities oversee medical device clinical trials by conducting on-site inspections not only of the clinical trial sites but also of the clinical trial projects. On 12 June 2024, NMPA released the Key Points and Determination Principles for the Inspection of Medical Device Clinical Trial Projects (Draft for Comments). Compared to the current effective version from 2018, this draft adds and details the key points for clinical trial project on-site inspections, aiming to provide better supervision of the conduct of clinical trial projects.

Human Genetic Resources

In recent years, the regulatory framework for human genetic resources (HGR) in China has become increasingly mature. Regulatory authorities have issued and updated a series of laws and regulations, including the Regulation on the Administration of Human Genetic Resources (HGR Regulation), the Implementation Rules on the Administrative Regulations on Human Genetic Resources (Implementation Rules), the corresponding administrative guidelines, as well as the Answers for Frequently Asked Questions on HGR Administration. The regulatory system for HGR in China has been thereby refined.

The State Council issued the 2024 revision of the HGR Regulation on 10 March 2024, which came into effect on 1 May 2024. Compared to its 2019 version, the new HGR Regulation has changed the regulatory authority from MOST to NHC.

Although the regulatory authority has been changed, without official amendments to the Biosecurity Law, the regulatory framework for HGR in China will not be significantly impacted. The application procedure and management system for HGR projects remains unchanged in practice.

After taking over, NHC has been commencing the revision of the Implementation Rules, where it may consider further streamlining the application process for HGR. If the application requirements and standards for HGR projects are relaxed in the future, it may further facilitate the ongoing and future research projects.

Ethics review

On 8 October 2023, the Measures for Ethics Review of Science and Technology (Trial) ("Ethics Review Measures") were jointly published by MOST and the other nine national departments. Since the draft of the Ethics Review Measures was released for public comments last year, the life sciences industry, including those involved in medical device research and development, has shown significant interest.

The Ethics Review Measures have proposed the implementation of a relatively new concept

of scientific ethics review with a wide-ranging scope. The application scope mainly includes the following.

- Scientific and technological activities involving humans as research participants, including those using humans as subjects for research activities such as testing, investigation, and observation, as well as those using human biological samples, and personal information data.
- Scientific and technological activities involving animals used in experiments.
- Scientific and technological activities that do not directly involve humans or experimental animals, but may pose ethical challenges in areas such as life and health, ecology, public order, and sustainable development.
- Other scientific and technological activities that shall be subject to ethics review according to laws, administrative regulations, and national regulations.

To comply with the Ethics Review Measures, medical device enterprises shall be responsible for conducting scientific ethics reviews for the applicable activities, and enterprises engaged in "ethically sensitive activities" must establish their own in-house scientific ethics committees. However, the regulatory authorities have not yet clarified the scope of "ethically sensitive activities", and official detailed guidance for enterprises to establish in-house scientific ethics committees is still under development.

LDTs

The regulatory framework for China's laboratory developed tests (LDT) industry continues to mature, marked by significant advancements in recent years. In early 2023, NMPA and NHC jointly issued the Notice of Carrying Out the Pilot Programme of Development and Use of Medical Institution Developed In Vitro Diagnostic Reagents, followed by Shanghai's Implementation Plan for the Pilot Programme in March 2023. These pilot regulations offered comprehensive and detailed guidelines on the allocation of responsibilities among regulatory authorities, the scope of pilot hospitals and the requirements for using LDT products. These efforts have provided an important blueprint for developing a mature LDT regulatory system in China.

The industry is expecting the further expansion of the LDT pilot programme to cover a broader range of institutions and regions, which could facilitate the growth and innovation within the LDT industry in China.

Registration

Localisation of imported medical devices

In recent years, China has been encouraging the market registration of domestic medical devices, particularly the localisation of imported medical devices. For medical device enterprises, the localisation of imported medical devices can both reduce the manufacturing costs and provide a significant advantage in government procurement. Due to these advantages, the localisation of imported medical devices has become an industry trend.

To encourage the localisation of imported medical devices, NMPA issued the Announcement on Matters Related to the Manufacturing of Imported Medical Devices by Domestic Enterprises on 18 September 2020. This announcement provides a special acceleration registration pathway for Class II and Class III domestic medical devices that have corresponding imported medical devices already approved for marketing. The key points of the announcement include the following.

- The applicant shall be a foreign-invested enterprise of the registrant of the corresponding imported medical device. However, the minimum shareholding ratio of the import medical device registrant in such foreign-invested enterprises has not been explicitly specified, leading to varying requirements in different provinces.
- Under the special acceleration pathway, for the review materials, research materials, clinical evaluation materials, and product risk analysis materials of the medical devices, the applicant can submit the original application materials submitted in the registration process of the corresponding imported products, provided that the aforementioned materials are relevant to and can support the ongoing registration application.
- The applicant shall ensure that the domestic manufacturing includes the primary manufacturing processes of the products and shall commit that the main raw materials and manufacturing processes are the same as those of the imported products.
- Contract manufacture cannot be applied under the special acceleration pathway.

In practice, a number of Class II and Class III medical devices have completed the localisation through this special acceleration pathway in recent years.

Classification

The classification of medical devices is fundamental in regulation. In recent years, China has continuously advanced the reform of its medical device classification system. The classification rules and catalogues have been revised in a timely manner, leading to enhanced regulatory efficiency.

With the rapid development of technology and the medical device industry, new challenges and requirements have emerged for regulatory work. There is a need to further optimise the classification system of medical devices. NMPA issued the Opinions on Further Strengthening and Improving the Classification Work of Medical Devices on 14 July 2023. The document has put forward certain requirements such as refining classification principles, revising and improving the classification catalogue, and optimising the procedures for classification determination.

In addition, on 10 May 2024, NMPA issued the Announcement on Regulating the Classification Determination of Medical Devices, which will officially replace the 2017 Notice on Regulating the Classification of Medical Devices on 1 September 2024. Compared with the 2017 Notice, the new announcement has made the following improvements:

- specifies that the medical products regulatory authorities shall provide classification determination services to medical device registration/filing applicants, and further clarifies the responsibilities of the regulatory authorities involved;
- improves the application pathways and procedures for classification determination;
- eliminates the requirement for submitting paper application materials, achieving full electronic processing of the classification determination;
- provides more detailed requirements for application materials; and
- strengthens the supervision of the implementation of the classification work.

Manufacturing

The Regulation on the Supervision and Administration of Medical Devices revised in 2021 has

officially adopted the Chinese version of the Market Authorisation Holder (MAH) system for medical devices nationwide, while also recognising the arrangements for contract manufacturing.

To further strengthen the regulation of contract manufacturing, NMPA issued the Announcement on Further Strengthening the Supervision and Management of Contract Manufacturing by Medical Device Registrants on 2 April 2024. The announcement:

- emphasises the detailed responsibilities of medical device registrants, which mainly includes establishing and maintaining an effective quality management system that covers the entire life cycle of medical devices, strengthening adverse event monitoring, prioritising CMOs with high-quality management standards, large production scales, good credit records, and high levels of manufacturing automation and information management;
- continuously regulates the management of the registration approvals for contract-manufactured medical devices, which mainly includes strengthening the management of the amendments to the registration approvals and strictly implementing the quality management system verification requirements; and
- emphasises that the regulatory authorities shall continuously strengthen the supervision and management of contract manufacturing of medical devices.

Distribution

Good Supply Practice

To further regulate the distribution of medical devices, NMPA released the new version of Medical Device Good Supply Practice (GSP) on 4 December 2023. The new GSP, which replaces the 2014 version, was officially implemented on 1 July 2024. Compared to the 2014 version, the new GSP introduces several significant changes.

- A new chapter, "Chapter II, Establishment and Improvement of Quality Management System", is included in the GSP. The new chapter emphasises that medical device distributors shall establish and maintain a robust quality management system, fulfil their legal responsibilities for medical device quality and safety, and continuously improve their quality management system. It is worth noting that the 2014 version of GSP only explicitly required Class III medical device distributors to submit annual self-inspection reports regarding their quality management. However, the new version of GSP also includes enterprises engaged in the distribution of Class II medical devices in the requirement to submit annual self-inspection reports.
- In response to new situations in practice, the new GSP has clarified that automatic vending machines for medical devices are considered as the extension of medical device retail business premises. Their location and quantity shall be commensurate with the management capabilities of the medical device distributors.
- The nationwide or regional multi-warehouse collaborative logistics management model has been included in the new GSP. It has been clarified that medical device distributors can establish warehouses across administrative regions or entrust companies that provide medical device transportation and storage services to store their medical device products. Medical device distributors shall strengthen the quality management for warehouses set up across administrative regions.
- It is clarified that in special situations such as disasters, epidemics, emergencies and clinical urgent treatments, or when only distributing large medical equipment such as

magnetic resonance imaging devices, medical device distributors may adopt a direct transfer method for the purchase and sale of medical devices. This allows the medical devices to bypass the distributors' warehouses and be sent directly from the supplier to the purchaser, provided that the safety of the purchase and sale channels and the product quality traceability are ensured.

As an appendix to the Medical Device GSP, NMPA issued and implemented the On-site Inspection Guidelines for Quality Management of Enterprises Specialising in Medical Device Transportation and Storage Services on 17 May 2023. The guidelines apply to regulatory authorities' on-site inspections of enterprises specialising in medical device transportation and storage services. The guidelines clearly state that such enterprises shall establish and maintain a quality management system appropriate for the medical devices they transport and store, while ensuring effective implementation.

Temporary Importation of Medical Devices Urgently Needed for Clinical Use

To regulate the application, review, and management activities of temporary importation of medical devices urgently needed for clinical use by medical institutions, NMPA issued the Management Requirements for Temporary Importation of Medical Devices Urgently Needed for Clinical Use by Medical Institutions (Draft for Comments) on 18 October 2023, seeking public comments. The draft applies to medical devices that are:

- temporarily imported for urgent clinical needs by medical institutions;
- already marketed abroad but no similar products have been approved for marketing in China; and
- used for the prevention and treatment of life-threatening diseases for which there are no effective domestic treatments or preventive measures.

The draft specifies that the medical institutions using these medical devices shall be qualified as Class III Grade A hospitals. For medical devices that meet the criteria for the temporary importation, after the application by the medical institutions, and upon approval from NMPA and NHC, the medical device distributors can apply for a one-time import customs clearance with the reply letter from NMPA. Compared with the conventional imported medical device marketing approval procedure, the application process and review time for the temporary importation are significantly simplified and shortened.

Advertisement and promotion

To better regulate internet advertising in the internet age, SAMR released the Measures on the Administration of Internet Advertising on 25 February 2023. This regulation has clarified and detailed the compliance requirements for internet advertisements and the obligations and responsibilities of various participants such as advertisers, advertisement publishers and internet platforms. The Measures on the Administration of Internet Advertising officially came into effect on 1 May 2023.

Regarding medical device advertisements, the Measures on the Administration of Internet Advertising have continued to enforce stringent regulatory requirements in the industry. They reiterate the key compliance requirements mentioned in other applicable regulations, such as the 2019 Interim Administrative Measures on the Review of Advertisements for Drugs, Medical Devices, Health Foods, and Food Formulas for Special Medical Purposes.

In 2023, SAMR also released the Administrative Measures on the Review of Advertisements for Drugs, Medical Devices, Health Foods, and Food Formulas for Special Medical Purposes (Draft for Comments), which is the revision of the existing regulation since its promulgation in 2019. To respond to practical needs, this draft introduces several provisions in livestream advertisements and those with website links and QR codes. The draft has also specified new requirements in labelling obligations and clarified procedures of advertising approval. Once the draft is implemented, China's regulation of medical device advertisements will be more comprehensive.

On 18 September 2023, NMPA released the Quality Management Standards for Online Sales of Medical Devices (Draft for Comments). Once implemented, they would be the first quality management standards specifically targeting online medical device distributors and platform operators.

Notably, the draft clearly stipulates regulations regarding the increasingly active practice of live-stream promotion. Some of the key requirements include the following.

- Online medical device distributors who promote their products through live-streaming must issue an authorisation letter to the live-stream promotion personnel. The authorisation letter shall specify the types of products being promoted and the duration of the authorisation. Additionally, the distributors must strengthen the training and management of live-stream promotion personnel and assume legal responsibility for the live-stream promotion activities conducted on behalf of the enterprise.
- Medical devices promoted to consumers through live-streaming must be medical devices for personal use.
- Online medical device distributors who promote their products through methods such as live-streaming and group buying must prominently display relevant information or links to such information on their web-pages. The information that needs to be displayed mainly includes the distributors' information, complaint channels, and product information.
- Platform operators providing live-stream promotion services must retain the live-stream videos of medical device promotional activities conducted on their platform. These videos must be kept for at least three years from the end date of the live-stream.

Post-marketing vigilance

China has always placed great importance on post-market vigilance of medical devices to continuously ensure their safety.

Since 2019, with the strengthening of the responsibilities of medical device registrants, China has successively issued several documents to improve the regulatory requirements for monitoring medical device adverse events. Such documents mainly include the 2019 Measures for the Monitoring and Re-evaluation of Medical Device Adverse Events, the 2020 Guidelines for Medical Device Registrants to Conduct Adverse Event Monitoring, and the 2021 Key Points for the Inspection of Adverse Event Monitoring by Medical Device Registrants.

In 2024, NMPA has drafted the pilot version of the Medical Device Good Vigilance Practice (GVP) and has gradually initiated pilot projects for medical device vigilance. In future, China's regulation on medical device vigilance will be guided by more comprehensive guidelines.

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