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China: Trends and Developments

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Trends and Developments

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Current Developments in Regulation for Medical Devices in China

In the year 2022–2023, 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).

China has been continuously exploring innovation of the regulatory system of medical devices. The Regulation on the Supervision and Administration of Medical Devices revised in 2021 ("2021 Regulation") has officially adopted the Chinese version of the Market Authorisation Holder (MAH) system for medical devices nationwide. Accordingly, several supplementary policies have been revised in 2022 to implement the MAH system specifically in the research and development (R&D), manufacturing, and distribution segments of the entire life cycle of medical devices. In addition, a number of industrial policies regarding such aspects as cross-border contract manufacturing and laboratory-developed tests (LDTs) were released during the past year, indicating the vitality of China's medical device industry.

At the same time, China continued to enhance its multidirectional supervision and regulation in the life sciences sector. Compliance issues such as human genetic resources (HGRs), research ethics, data security, and advertising and promotion have been the focus of regulatory enforcement.

It is also noteworthy that China has been working on the pre-legislative study of a new Medical Device Administrative Law, which, if released, will replace the 2021 Regulation to become the highest level of laws in the regulatory regime of medical devices. Compared with the Drug Administrative Law, which was legislated by China's top legislature, the National People's Congress (NPC) and its standing committee, the 2021 Regulation was only promulgated by the State Council, and there is currently no "law" in China for medical devices. If the Medical Device Administrative Law enters the formal legislative stage in the future and is promulgated by the NPC standing committee, it will be equivalent to the Drug Administrative Law in regulations on drugs and become the highest-level regulation governing medical devices in China.

Implementation of the MAH system

Research and development

NMPA and NHC announced the updated Good Clinical Practice for Medical Device Trials ("Revised GCP") in response to certain requirements specified under the 2021 Regulation. The Revised GCP has provided responses to certain issues and pain points in the medical devices R&D, and its major highlights include the following.

- The clinical practice for in vitro diagnostic (IVD) reagents is governed by the Revised GCP to align with the 2021 Regulation, where IVD reagents have fallen under the definition of medical devices. Nevertheless, IVD reagents regulated as drugs and LDTs that need not undergo clinical trials are not subject to the Revised GCP.
- The responsibilities of sponsors have been emphasised, accommodating the MAH system established by the 2021 Regulation. Since the MAHs are ultimately responsible for the entire life cycle of medical device products, they shall bear a series of responsibilities during clinical trials.
- The procedure of serious adverse event (SAE) reporting has been modified. The sponsors are the persons responsible for reporting

SAEs to the regulatory authorities. The time limit for such SAE reporting has also been clarified.
- The requirements on the record keeping of clinical trials have been enhanced by further including ethics committees' obligations to keep the records of ethics reviews.

Manufacturing and distribution

SAMR released the Measures for the Supervision and Administration of Medical Device Manufacturing and the Measures for the Supervision and Administration of Medical Device Distributions, which serve as supporting documents for the 2021 Regulation and effectively contribute to the distribution and manufacturing segments of the entire life cycle of the medical device regulatory system. Major highlights under these documents include the following.

- The enforcement of the MAH system is enhanced through the clarification of contract manufacturing arrangements and contract sales arrangements. The MAH system acknowledges that the manufacturer of medical devices can be different from the registrant. It is further emphasised that the MAHs shall be ultimately responsible for the quality and safety of medical devices under contract manufacturing and shall enhance the management of contract manufacturing organisations (CMOs). Similarly, with respect to distributions, the MAHs can sell their products either by themselves or by contract sales organisations (CSOs). In each case, the MAHs shall be ultimately responsible for the quality and safety of the products.
- Certain regulatory requirements have been simplified. Several documents are exempt from the applications of manufacturing approvals/filings and distribution approvals/filings, and the review period for approvals has been shortened from 30 business days to 20 business days, which significantly facilitates the application process.
- The supervision measures and applicable penalties for medical device manufacturing and distribution have been clarified. The MAHs, CMOs and distributing companies are required to submit annual self-examination reports to competent authorities regarding their quality management situations. Credit records are established for the MAHs, CMOs, and distributing companies, and information such as misconduct and complaints will be recorded. Moreover, such measures have further specified the circumstances of non-compliance and breaches to several obligations and the corresponding administrative penalties.

Innovation in regulatory policies

New policies regarding cross-border contract manufacturing

China is on its way of exploring the cross-border contract manufacturing of medical devices by initiating pilot policies within the Guangdong–Hong Kong–Macao Greater Bay Area ("Greater Bay Area"). In 2022, NMPA issued the Implementing Plan on Encouraging Medical Device MAHs in Hong Kong or Macao to Delegate CMOs in Nine Cities in Guangdong ("Implementing Plan").

The Implementing Plan applies to medical devices owned and manufactured by companies legally registered in Hong Kong or Macao, which have obtained market authorisations in the Chinese Mainland and are not prohibited by regulations from conducting contract manufacturing. The CMOs to be delegated shall have both their registered business addresses and manufacturing sites located in the nine cities in Guangdong (ie, Guangzhou, Shenzhen, Zhuhai,

Foshan, Huizhou, Dongguan, Zhongshan, Jiangmen, and Zhaoqing) and shall have compatible quality management systems and manufacturing capabilities. The Implementing Plan emphasises that the MAHs shall be responsible for quality management of the entire life cycle of their medical device products under such contract manufacturing arrangements.

This pilot policy can be deemed as China's first step in exploring cross-border contract manufacturing of medical devices. It offers more options for foreign medical device MAHs to choose their CMOs and facilitates the localisation of foreign medical device products without registering them as domestic products. It can be expected that more similar policies will be made in the future and, finally, the cross-border contract manufacturing of medical devices will be formally adopted by national legislation.

New policies regarding LDTs

In recent years, China has been actively exploring regulations for LDTs. Of particular significance, in early 2023, the NMPA and the NHC jointly issued the Notice of Carrying Out the Pilot Programme of Development and Use of Medical Institution Developed In Vitro Diagnostic Reagents. Additionally, in March, the Shanghai Medical Product Administration and the Shanghai Health Commission jointly issued the Implementation Plan for the Pilot Programme of Development and Use of Medical Institution Developed In Vitro Diagnostic Reagents. These two pilot regulations provide comprehensive and detailed guidelines on the allocation of responsibilities among regulatory authorities, the scope of pilot hospitals and varieties, as well as the requirements for the use of LDT products.

The issuance of these pilot regulations provides an important blueprint for the development of a mature LDT regulatory system and paves the way for future exploration. As the regulatory framework for the LDT industry continues to mature, the firm believes that China's LDT industry is looking towards an even more promising future.

New policies regarding DTx

Digital Therapeutics (DTx) refers to evidence-based therapeutic interventions driven by software aimed at preventing, managing, or treating medical conditions. China's DTx industry is in its early stage of development and exhibits immense potential and vitality. In practice, many DTx products have chosen to register as medical devices to facilitate commercial operations.

At both the local and national levels, policies supporting the development of the DTx industry have been continuously introduced. At the local level, in October 2022, Hainan introduced supportive policies for the DTx industry, which was the first comprehensive support policy for the entire life cycle of DTx products in China and even globally. It provides comprehensive policy support for DTx products, encompassing fields such as R&D, regulatory registration, business operations, and medical insurance reimbursement. Several other cities, including Hangzhou and Hunan, have also implemented favourable policies to facilitate the development of DTx products. At the national level, according to the announcement by the National Institutes for Food and Drug Control (NIFDC) in September 2022, the NMPA is in the process of establishing guiding principles for digital therapy classification; this would provide further support for the standardisation and success of DTx products in China.

New trend of domestic substitution

The promotion of domestic substitution in medical devices has already been reflected in Chinese regulatory policies, while in practice, the current rate of domestic substitution in medical devices in China is not particularly significant, and high-end medical devices still heavily rely on imports. However, on 15 July 2022, the Ministry of Finance issued a notice seeking public comments on the revised draft of the Government Procurement Law, which explicitly includes "supporting domestic industries" as a government procurement policy for the first time in Chinese law. If this draft is enacted, the trend of "domestic substitution" in medical devices may further accelerate, which will have much more impact on the device industry.

Notably, there are significant uncertainties in determining whether a medical device qualifies as "domestic". For instance, devices assembled and registered domestically using components of imported medical devices or devices manufactured domestically by foreign-invested enterprises may also be considered domestic medical devices. The specific criteria depend on the regulatory practices, and further observation is needed.

Multidimensional regulatory requirements

Regulation of human genetic resources

MOST issued Implementing Rules on the Administrative Regulations on Human Genetic Resources ("Implementing Rules") on 1 June 2023, which became effective on 1 July 2023. The Implementing Rules have clarified many operational questions that have emerged since the Administrative Regulations on Human Genetic Resources became effective four years ago, which is welcomed by the entire life sciences industry. The medical devices R&D involving the use of Chinese HGRs will also be affected by the new Implementing Rules. The Implementing Rules will facilitate the medical devices R&D by a series of measures such as narrowing the scope of HGR information, narrowing the scope of foreign entities that will be strictly limited for carrying out certain HGR-related activities, and expanding the scope of international collaboration with clinical trials that can be subject to the notice-filing procedure instead of the approval procedure. Meanwhile, supervision and inspection with respect to HGR compliance have also been enhanced.

Regulation of ethics review

On 27 February 2023, NHC, together with other departments, issued the Measures for the Ethics Review of Life Sciences and Medical Research Involving Humans ("Measures"). The Measures represent the updated and latest ethics review measures led by NHC, following the Ethics Review Measures for Biomedical Research Involving Humans seven years ago. The Measures include several notable provisions. First, they expand the scope of ethics reviews by including all life sciences research involving humans, in addition to medical research. They also strengthen requirements for the protection and regulation of biological samples, such as requiring the submission of proof regarding the source of biological samples and information data as part of the ethics review of materials. Furthermore, they enhance protection requirements for vulnerable populations, for instance, by stipulating that informed consent must be obtained again when the civil capacity of research participants advances. Additionally, the Measures allow for a system of delegated review, providing a regulatory foundation for companies to conduct relevant research through delegated ethics reviews. They also optimise the ethics review procedures, including provisions for exempting specific research from an ethics

review. Ethics review requirements for life sciences and medical research involving humans have undergone a revitalising transformation following the implementation of the Measures.

Additionally, it is noteworthy that on 4 April 2023, MOST published the Measures for Ethics Review of Science and Technology (for Trial Implementation – Draft for Comments). The draft proposes the implementation of a relatively new concept of scientific ethics review with a wide-ranging scope. Once finalised, medical device enterprises will be responsible for conducting scientific ethics reviews for applicable activities, and enterprises engaged in ethically sensitive activities must establish their own in-house scientific ethics committees. However, the draft does not clarify what constitutes "ethically sensitive activities", and it remains unclear how the draft will be reconciled with other existing ethics review rules issued by NHC and other entities in the future.

Regulation of personal information protection and data security

After the implementation of the Personal Information Protection Law and the Data Security Law, there has been a comprehensive and rapid development of regulatory supervision over data since 2022. Issues such as personal information protection and cross-border data transfer are prominent topics in the field of data compliance, requiring careful attention in the processes of collecting, transferring, and processing medical device data.

Regarding personal information protection, regulatory requirements have been continually strengthened. For example, the newly introduced Measures reflect the enhanced requirements for personal information protection, explicitly providing for the expansion of information disclosure to research participants to include details such as whether research data will be shared and reused. Additionally, the national standard of the Implementation Guidelines for Informing and Obtaining Consent in Personal Information Processing has been introduced to provide more unified guidance for the implementation of informed consent.

Regarding cross-border data transfer, regulatory authorities have successively issued regulations such as the Measures for Security Assessment for Cross-Border Data Transfers, Application Guidelines for Security Assessment for Cross-Border Data Transfer (Version 1.0), the Measures for the Standard Contractual Clauses for the Cross-border Transfer of Personal Information, and the Technical Specification for Certification of Cross-Border Transfers of Personal Information ("Certification Specification Version 2.0"). The supporting system for the three paths of cross-border data transfer under the Personal Information Protection Law has been successively introduced, with each path having relatively clear operational requirements. It is expected that the regulation of the "three-pronged approach" to cross-border data transfer will become clearer and more operationally feasible in the future.

Regulation of medical device advertising and promotion

Since 2022, there has been a trend towards in-depth refinement in the regulation of medical device advertising and promotion, following the introduction of the Measures on the Administration of Internet Advertising and the release of the Administrative Measures on the Review of Drug, Medical Device, Health Food, and Food Formulas for Special Medical Purposes Advertisements (Draft for Comments) ("Advertising Opinion Draft").

For instance, the Measures on the Administration of Internet Advertising have further refined regulatory requirements prohibiting the publication of medical device advertisements in a disguised manner. They stipulate that health and wellness-related information should not appear on the same page or at the same time as the address, contact information, shopping links, and other details of the medical device business operator. In the case of disguised advertising, the advertising approval should be obtained beforehand, and the word "advertisement" should be prominently displayed on the advertising page. The Measures also emphasise the prohibition of advertising medical devices on websites, web pages, internet applications, WeChat official accounts, and other online media targeting minors. The Advertising Opinion Draft also refines regulatory requirements for medical device advertisements, such as explicitly stating that such advertisements shall not include any contents that encourage consumers to use medical devices arbitrarily or excessively.

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