China Released Draft Medical Device Law for Comments

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On August 28, 2024, the National Medical Products Administration (**NMPA**) released the Medical Device Administration Law (Draft for Comment) (hereinafter referred to as the "**Draft**") for public comments. This move comes within a year of the Standing Committee of the National People's Congress's adding the Medical Device Administration Law to its legislative plan on September 7, 2023, reflecting the regulatory body's efficient and high-quality advancement of the legislation, indicative of its commitment and diligence.

The forthcoming Medical Device Administration Law is anticipated to significantly impact the medical devices industry. Unlike the drug sector, which is governed by the Drug Administration Law, China's medical devices regulation has primarily relied on the State Council's Medical Device Supervision and Administration Regulation, an administrative regulation, not a law. The lower legal hierarchy of administrative regulations has limited the depth and refinement of the regulatory framework. The new Medical Device Administration Law is expected to provide a more authoritative regulatory framework for the industry.

Having contributed to preliminary legislative study and consultation for the Draft, we analyze and interpret several regulatory changes and key points in the Draft, drawing on our team's prior research. We aim to provide useful insights for industry stakeholders regarding the evolving regulatory landscape in China's medical device sector.

Medical device registrants and filers

The Draft clearly stipulates in Article 7 that the registrant and filer system, not the Marketing Authorization Holder (**MAH**) system, for medical devices will continue, aligning with the current regulatory framework. However, we understand that during the drafting stage, there was some industry discussion about whether the Medical Device Administration Law should reference the MAH system used in the Drug Administration Law. The industry has also deliberated on how to distinguish the legal obligations of Class I medical device filers from those of MAHs if the MAH system were to be applied to medical devices.

The Draft maintains the registrant and filer system for medical devices, instead of adopting the MAH terminology. Nevertheless, the Draft aligns the responsibilities of medical device registrants and filers closely with those of MAHs under the Drug Administration Law, requiring them to bear legal responsibility for the safety and efficacy of medical devices throughout their entire lifecycle, including research and development, manufacturing, distribution and use. Compared to the previous Medical Device Supervision and Administration Regulation, which only listed several specific obligations, the Draft imposes broader and more comprehensive obligations on medical device registrants and filers, emphasizing their primary responsibility.

Transfer of marketing approvals

A notable development is that Article 58 of the Draft explicitly permits the transfer of medical device marketing approvals. The current regulatory framework lacks a clear pathway for such transfers, which has been a topic of significant interest and discussion. If implemented, this provision will legally establish the feasibility of transferring medical device marketing approvals.

Currently, due to the lack of policies, medical device marketing approvals cannot be transferred in practice. Notably, for transitioning imported medical devices to domestic products, the NMPA's Announcement No. 104 [2020] (commonly known as "**Announcement No. 104**") has streamlined the registration procedures for the domestically manufactured version of medical devices by accepting the registration materials and documents from the corresponding imported medical devices. However, this pathway still involves two separate registrations for the imported product and the domestic product, rather than a true "transfer" of one marketing approval.

The Draft brings hope for establishing a clear pathway for the transfer of medical device marketing approvals, though it has not yet differentiated between various transfer scenarios (domestic products to domestic products, imported products to imported products, or imported products to domestic products) or provided specific operational requirements. We look forward to the finalization of this provision and the subsequent introduction of supporting regulations.

Mandatory standards

A highlight of the Draft is the dedicated chapter on standards and classification of medical devices. This chapter is strategically positioned immediately after the general provisions in Chapter 2, underscoring the importance of standardization and categorization in regulating medical devices. Compared to the Medical Device Supervision and Administration Regulation, the Draft removes references to mandatory industry standards for medical devices. Specifically, the Medical Device Supervision and Administration Regulation requires that medical devices comply with mandatory national standards or, in their absence, mandatory industry standards. The Draft excludes references to mandatory industry standards, limiting the scope of applicable mandatory standards to national standards only.

Prior to the release of the Draft, the industry has long been advocating for the relaxation of mandatory standards for medical devices and the harmonization of the management system of medical device standards with the Standardization Law. The Draft addresses these discussions by restructuring the

management system to be consistent with the principle in the Standardization Law that mandatory standards exist solely at the national level, while industry standards are only recommended.

Managing medical device standards entails a long-term and complex process. It remains to be seen whether mandatory industry standards will gradually be differentiated, with critical health and safety requirements elevated to mandatory national standards, while others are converted into recommended industry standards in line with the spirit of the Standardization Law. How the existing mandatory industry standards will be handled after the finalization and implementation of the Draft is worth the industry's attention.

Personal liability for executives

The Draft significantly increases the obligations and responsibilities of the legal representatives and key personnel of medical device registrants and filers. It emphasizes that they must "take full responsibility for the quality of medical devices," "take full responsibility for the manufacturing activities within their enterprise," and "take full responsibility for the quality and use of medical devices within their institution." For the first time, the Draft provides that responsible personnel of entities could face detention of 5 to 15 days by public security authorities (i.e., the police) for various violations, including the manufacturing or distribution of medical devices that fail to comply with mandatory standards or approved technical requirements. If these provisions finally take effect, it will heighten the accountability of executives of medical device companies.

On one hand, regulatory authorities intend to strengthen the deterrence through increasing the severity of punishment on executives. On the other hand, we have observed instances in practice where companies faced penalties for post-market functional upgrades without adversely affecting the safety. We have conferred with various competent authorities and industry participants, expecting more flexibility in the enforcement of medical device regulations. We look forward to further clarifications on these related matters in future.

IVD/LDT

Article 104 of the Draft retains the provisions from the Medical Device Supervision and Administration Regulation regarding laboratory-developed tests (**LDTs)**. As an essential category of medical devices, commercialized in vitro diagnostics (**IVDs**) and LDTs have long been the focal points of legislative discussions, while many regulatory requirements await further clarification and standardization. We have also engaged in extensive discussions with industry participants on the market demands of IVDs and LDTs and have shared our points of view on the interpretation of regulation (e.g., our interpretation of the new LDT pilot regulations: "*New LDT Pilot Regulations: Key Takeaways*").

Although Article 104 of the Draft does not introduce significant changes, it still necessitates further detailed management measures to be issued by the drug regulatory and health authorities. We will continue to closely monitor subsequent changes and developments in regulatory requirements.

Liability of domestic agents

The Draft introduces the concept of "domestic responsible entity" and stipulates that domestic responsible entity of imported medical devices shall comply with many of the regulatory obligations and legal liability requirements applicable to registrants and filers, sharing joint liability with them. This arrangement aligns with the Drug Administration Law, which requires the Chinese domestic agencies to share joint liability with the MAH. Additionally, the Draft enhances the qualification requirements for domestic responsible entities. Unlike drug regulations, which do not specify such requirements, the Draft explicitly requires that domestic responsible entities have already obtained medical device manufacturing or distribution licenses and further clarifies their specific assistance obligations.

These provisions further clarify the legal status and responsibilities of domestic responsible entities, potentially enhancing regulatory enforcement and stability. If enacted, future commercial collaborations between foreign and Chinese medical companies will need to place greater emphasis on the selection and arrangement of registrants, filers, and domestic responsible entities.

Import and export

The Draft introduces a new Chapter 6 dedicated to the import and export of medical devices, enhancing the management system for medical devices. Notably, the Draft addresses a previously discussed industry concern regarding the responsibilities of domestic responsible entities towards parallel imports. Specifically, Article 89 of the Draft requires that imported medical devices undergo customs clearance based on the written authorization of their domestic responsible entities. This will enhance the oversight and control exerted by domestic responsible parties over the parallel importation of medical devices.

Additionally, the Draft places special emphasis on the regulation of cross-border e-commerce retail for medical devices. It mandates the designation of a domestic corporate entity as the domestic service provider, without which products cannot clear customs. This will strengthen regulator's oversight of cross-border e-commerce retail service providers for medical devices.

Clinical trials

It is encouraging that Article 38 of the Draft reduces the approval time for medical device clinical trials from 60 working days to 30 working days. The 60-day implied approval system for drug and medical device clinical trials, as a significant outcome of China's deepening system reform, has notably accelerated the clinical trial review process. In July 2024, the NMPA issued new regulations proposing to complete the review and approval of innovative drug clinical trial applications within 30 working days. The Draft aligns with this initiative, further reducing the approval time for medical device clinical trials to 30 working days, fully reflecting China's enhanced regulatory review capabilities and its commitment to promoting product development.

Moreover, Article 43 of the Draft explicitly encourages the conduct of international multicenter clinical trials for medical devices and advocates for the development of regional ethical review systems. This initiative aims to further facilitate regional and international cooperation, thereby promoting innovation in the global medical device industry.

Contract manufacturing

Article 69 of the Draft places special emphasis on the manufacturing release requirements within the scope of contract manufacturing arrangements. In the absence of provisions in the current medical device and drug regulations, the Draft explicitly requires medical device registrants and filers to review the manufacturing release procedures of their contract manufacturers and to oversee the release of each batch of products. This further delineates the responsibilities of medical device registrants and filers in ensuring the quality of contract-manufactured products.

Furthermore, in line with the ongoing regulatory emphasis on enhancing personal accountability, the Draft also stipulates that the legal representatives and key personnel of contract manufacturers take full responsibility for the quality management within their organizations.

Vigilance system

Chapter 8 of the Draft introduces the establishment of a medical device vigilance system. Historically, China has primarily implemented a medical device adverse events monitoring system. In recent years, with the guidance of scientific regulatory approaches, the concept of medical device vigilance has matured. The proposed vigilance system in the Draft requires medical device registrants and filers to take primary responsibility for product quality and safety. This system aims to enhance the monitoring, identification, assessment, and control of adverse events and other harmful incidents related to the use of medical devices that result in or may result in harm to human health, thereby establishing a comprehensive vigilance framework.

Since 2024, the NMPA has been drafting the Good Vigilance Practice for Medical Devices (Pilot) (**GVP**) and has initiated pilot projects for medical device vigilance. Following the implementation of the Good Vigilance Practice for Drugs in 2021, it is anticipated that China will soon see the formal establishment of legal frameworks and GVP guidelines for medical device vigilance.

Conclusion

This article breaks down key aspects of the Medical Device Administration Law (Draft for Comment) to help industry practitioners better understand the latest regulatory trends, clearly comprehend the changes in regulatory requirements, and capitalize on new opportunities for industry growth.

We will keep a close watch on the legislative progress of the Medical Device Administration Law, actively participate in related research and discussions, and anticipate the establishment of a scientific top-level regulatory framework for the medical devices industry in the near future. We will keep monitoring the regulatory developments and promptly share our insights.

Important Announcement

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