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China Unveils New Medical Device Regulations

The Chinese State Council has passed new Medical Device Regulations (State Council Order #739) to replace the existing Medical Device Regulations (State Council Order #680). Order #739 was recently published by the National Medical Products Administration (NMPA) and will become effective on June 1, 2021. Order #739 largely follows the legislative structure of Order #680, but the underlying regulatory philosophy has become more progressive.

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Highlights of Order #739 can be grouped under four main themes.

1. Balancing clinical needs and risks.

- Conditional approvals will be made available for devices treating rare diseases, critical diseases that do not have an effective treatment method or responding to abrupt public health incidents. At the request of the National Health Commission, the NMPA can issue an emergency use authorization under public health emergency.
- The NMPA will waive clinical evaluation for mature products and products whose safety and effectiveness can be proven by means other than clinical evaluation (e.g., bench tests or animal studies). The NMPA will allow versatile clinical evidence to demonstrate product safety and effectiveness. Such evaluation can be based on clinical study data or analysis of clinical literature and clinical data on predicate devices.
- Expanded access to investigational devices will be made available for patients in the study sites upon ethics committee approval and the patients' giving informed consent, provided that the investigational devices are used for critical, life-threatening diseases without an effective treatment method and can confer clinical benefits on patients based on medical judgment.
- Distributors of certain Class 2 medical devices whose safety and effectiveness will not be affected by the distribution process can be exempted from filing a distribution record with local MPAs.
- Medical institutions will be allowed to use their lab-developed tests (LDTs) for their own clinical purposes if the clinical needs cannot be met by approved IVD reagents.
- Medical institutions will be allowed to import Class 2 or Class 3 medical devices in small quantities with a special import permit from the NMPA or NMPA-authorized local provincial MPAs to meet urgent clinical needs.

2. Encouraging innovation.

- One of China's national priorities is to transform from a leading manufacturing base to a strong innovation powerhouse in the medical technology space. Order #739 declares that the state will support innovation in medical technology by means of R&D funding, financing, government procurement and medical insurance reimbursement.
- Foreign manufacturers seeking approval for innovative imported medical devices that will be launched first in China will not need to present the country of origin (COO) approval at the time of marketing authorization application. The COO approval is still required for the issuance of marketing authorizations for other non-innovative imported devices.

- The Marketing Authorization Holder (MAH) system will be rolled out nationwide. Except for certain high-risk medical devices, contract manufacturing of medical devices will be permitted. MAHs can choose to focus on R&D and work with licensed device manufacturers on product manufacture.

3. Emphasizing MAH's compliance responsibilities

- MAHs will be responsible for the safety and effectiveness of their products during the entire product life cycle. They must establish a quality management system and ensure its effectiveness, define and implement a post-approval study and risk control plan, conduct adverse event monitoring and re-evaluation, establish and implement the product tracing and recall system, and fulfill other statutory obligations imposed by the NMPA.
- Order #739 significantly increases MAH's liabilities for non-compliance. For example, the manufacture and distribution of unapproved medical devices can lead to fines in the range of 15-30 times the sales value (as opposed to 10-20 times the sales value under Order #680). The manufacture and distribution of medical devices that do not conform to mandatory standards or NMPA-approved product technical requirements could result in fines in the range of 5-20 times the sales value (as opposed to 5-10 times the sales value under Order #680).
- Order #739 also introduces personal liability on the legal representatives, main responsible persons, directly responsible supervisors or other personnel of MAHs. The income of these individuals during the period of non-compliance can be confiscated. They will also receive an administrative fine up to three times their income and a permanent debarment from engaging in the manufacturing or distribution of medical devices under serious circumstances.

4. Re-positioning local legal agents

- Historically, foreign device manufacturers were required to appoint a Chinese legal entity as their local legal agents (also known as local legal deputies) in order to fulfill statutory obligations. These local legal agents also acted as the main point of contact for regulatory authorities in China, and their names would be listed on the medical device registration certificates. Under Order #739, foreign device MAHs will still need to appoint a Chinese legal entity to submit regulatory applications and correspond with regulatory authorities. Nevertheless, these local appointees will only play a secondary role to assist the foreign device MAHs in the performance of compliance obligations.
- While Order #680 does not differentiate the liability of local legal agents from the foreign device MAHs, Order #739 makes it clear that local appointees will assume a lesser degree of liability compared to the foreign device MAHs. If local appointees fail to perform the statutory responsibilities and obligations on behalf of the MAHs, they will only be subject to administrative fines up to RMB 0.5 million, and their responsible personnel will only be subject to a five-year debarment. In comparison, foreign MAHs who refuse to fulfill the administrative penalties can result in a ten-year import ban.

The promulgation of Order #739 provides a good opportunity for medical device companies to review their market entries and growth strategies in China. R&D-focused companies with a product portfolio that demonstrates clinical values will be able to take advantage of the new pathways to accelerate their time to market. Moreover, it will be critical for foreign medical device companies to select Chinese partners who have the necessary capabilities and a strong compliance culture to act as local appointees. Last but not least, Order #739 calls for a careful examination of companies' existing operations in China, as failure to address legacy issues can result in more serious consequences in the future.