FIVE THINGS TO KNOW ABOUT THE CHANGES TO CHINA'S MEDICAL DEVICE REGULATION

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China Corporate Alert

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On 18 March 2021, the State Council of China announced certain amendments (the 2021 Amendment) to the Regulation on the Supervision and Administration of Medical Devices (the Medical Device Regulation). The 2021 Amendment took effect on 1 June 2021. This was the third amendment to the Medical Device Regulation since 2000.

The 2021 Amendment is widely acknowledged as progressive and reflective of the advancement and innovations in the industry.

NATIONWIDE ROLLOUT OF MEDICAL DEVICE REGISTRANT SYSTEM

Previously a pilot program in 21 provinces and cities across China, the registrant-focused medical device system is now formally adopted nationwide. Our prior Alert on the marketing authorization holder (MAH) programs sets out details and the significance of this system, which includes, among other things, the flexibility for an MAH of a medical device to contract a qualified medical device manufacturer to manufacture medical devices in China, whereby the MAH is not required to have a medical device manufacturing license or a manufacturing facility in China.

FAST-TRACK APPROVALS

The 2021 Amendment contains an exemption for certain innovative foreign-manufactured medical devices to be registered with the National Medical Products Administration (the NMPA) and imported into China, without such medical devices having received a marketing authorization in their home country where they are manufactured. In addition, the NMPA can now grant special or conditional approval for the use of certain unregistered medical devices to counter public health emergencies or any rare, life-threatening illnesses that do not have an effective treatment.

REFORM IN CLINICAL EVALUATION

Clinical evaluation for registering a medical device in China can be satisfied through clinical trials or a desktop evaluation (based on compatible clinical data obtained from similar medical devices). Prior to the 2021 Amendment, a certain group of medical devices could be exempted from clinical trials but would still be subject to desktop evaluation. Under the 2021 Amendment, a certain qualified group of medical devices can be exempted from clinical evaluation entirely, i.e., clinical trials and desktop evaluation.

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The 2021 Amendment also confirms that patients suffering from life-threatening diseases without an effective treatment can participate in clinical trials of a medical device, and such data can be used for applying for registration of the medical device.

STREAMLINED PROCESS

The 2021 Amendment streamlined several aspects of the medical device registration process, such as: (a) an applicant of Class II and Class III medical devices may now choose to perform the testing and prepare the testing reports through their self-sourced testing centers as an alternative to testing done by NMPA-affiliated testing centers, (b) a distributor of Class II medical devices may now be exempted from the record-filing formality in certain circumstances, (c) a clinical trial application is deemed to have been approved by the NMPA if the NMPA does not respond within the official review period of 60 working days, and (d) the overall review time for manufacturing and distribution of license applications has been reduced from 30 to 20 working days.

ENHANCED PENAL SYSTEM

The 2021 Amendment added new categories of prohibited or restricted activities and significantly increased penalties over matters such as MAHs providing false or misleading application documents or failure to perform quality assurance obligations. For example, the ceiling for monetary fines for operating without a license has been increased from 10 times to 30 times the value of the product in question. Interestingly, the NMPA has also broadened its investigative powers to look at the sale of medical devices over e-commerce platforms.

The 2021 Amendment reflects the deepened reform in China's medical device industry to encourage innovation while balancing medical needs and clinical risks. It also provides certainty and opportunity in market entry to foreign manufacturers.

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