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NEWSLETTER – LEGAL INFORMATIONS
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Medical Device Registrant System in China

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This is the third in our series of newsletters on the regulation of medical devices in China, following the promulgation of the Regulations on the Supervision and Administration of Medical Devices, which came into force on 1 June 2021 (the "**2021 Regulation**").

We have previously looked at the broad outlines of the 2021 Regulation, before detailing the provisions on clinical evaluation and clinical trials. In this newsletter we will focus on the new registration system for Medical Devices ("**MD**").

The introduction of the MD Registrant System in China is one of the key point of the **2021 Regulation**. This corresponds to the concept of "marketing authorization holder" for pharmaceuticals.

What is the MD Registrant System? How does it work? What are the impacts of this new system for MD supervisions?

MD REGISTRANT SYSTEM UNDER THE 2021 REGULATIONS

Under the newly introduced MD Registrant System, the "marketing authorization holder" will be classified as **Registrant** for registration of Class II and Class III MD and **Filer** for record-filing of Class I MD.

An MD Registrant or Filer under the 2021 Regulations refer to a medical device company or medical device R&D institution. This enables R&D institutions with no manufacturing capacity to apply for registration or record-filing of MDs. With such, manufacturing capacity is no longer a premise for application for MD registration or record-filing under the 2021 Regulations (see elaborations on entrusted manufacturing in the last part).

RESPONSIBILITIES OF MD REGISTRANT OR FILER

Under the 2021 Regulations, MD Registrant and Filer are responsible for safety and effectiveness of MDs in the whole process (R&D, manufacturing, operation and use). Before the 2021 Regulations took effect, such responsibilities were borne respectively by either the manufacturer, the business operator, or the user subject to the Supervision and Administration of Medical Devices (2017 Revisions) ("2017 Regulations"). Under the 2021 Regulations, MD Registrant and Filer are responsible for safety and effectiveness of MDs in the whole process (R&D, manufacturing, operation and use). Before the 2021 Regulations took effect, such responsibilities were borne respectively by either the manufacturer, the business operator, or the user subject to the Supervision and Administration of Medical Devices (2017 Revisions) ("**2017 Regulation**s").

REGISTRANT OR FILER FOR IMPORTED MDS

For imported MDs, the Registrant or Filer will be the foreign entity. Foreign entities must appoint a Chinese entity (the "designated party", previously the "agent") to assist them in performing their responsibilities.

As provided on the website of national MPA ("**NMPA**"), information of the name and address of the MD Registrant or Filer, manufacturing address, name and address of its designated party and other MD product information will be gathered for such registration or record-filing of imported MDs.

Generally, under the Chinese legal regime, a principal takes responsibilities for the acts of its agent. Considering there were no legal consequences clearly provided for the "agent" before the 2021 Regulations, it was difficult for pursue legal responsibilities of the "agent". With such, the law-makers carefully replaced the concept of "agent" with "designated party" in the 2021 Regulations. The 2021 Regulations also set clear penalties for violations by the "designated party" as well as by the overseas registrant or record-filing party of MDs.

If the "designated party" fails to perform its assistance obligations, it can be imposed with corrections, warning, or a fine between RMB 50,000 and RMB 100,000 (under serious cases, a fine between RMB 100,000 and RMB 500,000). Moreover, the legal representative, principal or person directly in charge and other liable persons from the "designated party" can be banned from engaging in the manufacturing and business operation of MDs within five years.

If the overseas Registrant or Filer of such imported MDs refuses to perform administrative penalty, it will be banned from importing MDs within ten years.

ENTRUSTED MANUFACTURING (OEM)

As is stated under the first part, an MD Registrant or Filer is not mandatorily required to manufacture MDs on its own anymore. The 2021 Regulations clearly provide that an MD Registrant or Filer can entrust qualified third parties to manufacture such MDs. As the 2021 Regulations are effective nation-wide, such entrusted manufacturing is no longer restricted to certain pilot areas anymore.

To safeguard the product quality of such MDs, the 2021 Regulations provide that the Registrant or Filer of MDs are responsible for the quality of MDs manufactured under entrustment. The MD Registrant or Filer are required to enter into an entrustment agreement with the entrusted manufacturer. The entrusted manufacturer is required to organize manufacturing of such MDs in accordance with laws and regulations, Good Manufacturing Practices, compulsory standards, product technical requirements and the entrustment agreement.

There is one exception to the above: the manufacture of high risk, implanted medical devices cannot be entrusted and must be manufactured by the Registrant.

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The 2021 Regulation is a new step in China's ambitious regulatory process in the health sector. The growth prospects of the medical device market are immense and it is important for foreign medical device companies wishing to develop in China to master the regulatory aspect.

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