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NEWSLETTER – LEGAL INFORMATIONS
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New Measures on Medical Device - A More Opened Up but More Strictly Regulated Market

CHINA

On March 23rd, 2022, the State Drug Administration ("NMPA") issued the *Measures for the Supervision and Administration of Medical Device Manufacture* ("Manufacture Measures") and the *Measures for the Supervision and Administration of Medical Device Operation* ("Operation Measures") ("new measures"). Both measures came into force on May 1st, 2022.

The new measures make the manufacture and operation stages of medical device coherent with the *Regulation on the Supervision and Administration of Medical Devices* (the "Regulation") which was revised in 2021. Before the new measures, medical device companies often find themselves facing the uncertainty caused by the incoherence between the old Manufacture Measures and the Regulation. With the implementation of the new measures, the medical device companies are expected to have more flexibility and possibility in their business in China.

- **MORE OPEN UP FOR ENTRUSTMENT OF MEDICAL DEVICE MANUFACTURE AND OPERATION**

For a long time, in China, the registration (which involves research and development) and manufacture of medical device are tied together. Although manufacture entrustment is allowed in theory, because the entrusted company is required to hold a registration certificate already itself and only one entrusted company is allowed at one time, generally the manufacture entrustment is very difficult in practice. That means the company that registers the medical device mostly has to manufacture the medical device itself, which is sometimes not ideal, especially for research laboratories that do not have manufacturing capacities or foreign companies that have not set up factories in China yet.

In 2017, China started the trial for the Market Authorization Holder system of Medical device in Shanghai, which allows the separation of registration and manufacture of medical device. That trial was expanded to Guangdong and Tianjin in 2018. In 2021, after the revision of the Regulation, it is accepted legally that the Market Authorization Holder system is implemented in China. However, because the Production Measures and Operation Measures had not been updated accordingly then, there was a gap and incoherence within the Regulation and the measures, and medical device companies and factories often found the entrustment of manufacture lack guidance and thus not practical.

After the implementation of the Manufacture Measures this May, that incoherence has been eliminated, and medical device companies now can have more freedom as well as more clarification on the practical requirements of the entrustment of manufacture. For example, under Article 10 of the Manufacture Measures, the entrusted manufacture company is no longer required to have already held a registration certificate itself. The old requirement that the registration company can only entrust to one manufacture company has been deleted directly. That means the medical device register company now can have more choice on the manufacture factory and there is no limit on the number of manufacture factories they entrust. This opens up the possibilities for new business models, especially for companies with strong research and development abilities but do not have manufacture capacity yet in China.

The Manufacture Measures also specifies the requirements on the manufacture entrustment. For example, both parties are required to sign the manufacture quality agreement and entrustment agreement according to the NMPA quality agreement guideline (Manufacture Measures Article 32). Also, the entrusting company is responsible for the release of the medical device on the market. It should examine the release documents of the entrusted manufacture (Manufacture Measures Article 34).

- **SIMPLER ADMINISTRATIVE PROCEDURES**

Both the Manufacture Measures and the Operation Measures make the relevant administrative procedure simpler, which is another good news for the medical device market participants.

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For example, for both the medical device manufacture certificate and the medical device business operation certificate, the application material review time has been shortened from 30 business days to 20 business days. For Category I medical device, the company can make the manufacture record filing at the same time when it makes the record filing for the medical device. For certain listed medical devices, the record filing requirement at the operational stage is removed.

These reforms all make the administration work for medical device companies easier.

- **STRICTER SUPERVISION AND PENALTY**

While both measures allow more flexibility in the medical device market, it should be noted that they also impose strict supervision requirements and more severe penalties for companies violating the measures.

At the manufacture stage, for example, the Manufacture Measures established the reporting system, Article 45 provides that the registration company and the entrusting company should conduct self-checks on their quality management system every year and submit the self-check reports to the local NMPA. For entrustment, the entrusting companies remain liable for the safety of the medical device throughout the whole life circle of the medical device. Other systems such as detailed information publicity and interview with the managing personnel in case of high risks are also implemented in the Manufacture measures.

At the sales and operation stage, for example, the Operation Measures requires the local NMPA to establish the credit files of the medical device operation companies, which should archive the companies' past penalties, self-check reports, administrative inspection results, etc. Several new fine penalty provisions have been added to the Operation Measures too.

CONCLUSION

The new measures aim to have a more open up but also more regulated medical device market. As the implementation measures of the Regulation, on the one hand, they provide more flexibility and open up more business possibility for medical device companies. On the other hand, they impose stricter supervision and penalty upon the market participants when violating the rules. We suggest that the medical device market participants be well informed and prepared for the changes and explore new business growth with the flexibility the new measures provide.

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