IMPACT OF THE GROWING MARKETING AUTHORIZATION HOLDER PILOT PROGRAM IN CHINA'S MEDICAL DEVICE INDUSTRY

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This article reveals the mechanics of a growing pilot program for registration of Class II and Class III medical devices to be contract manufactured in China that has gained significant recognition across China over the past few years, and explores the implications that such a program has over Chinese and foreign manufacturers and research centers, particularly, the implications to a foreign manufacturer of medical devices.

BACKGROUND

Following the 2017 directive of the State Council of China to deepen the reform of China's medical device industry, the Shanghai branch of the food and drug regulator announced a marketing authorization holder (MAH) pilot program that regulates the registration of Class II and Class III medical devices (MAH Program) for the Shanghai Free Trade Zone. In 2018, the Tianjin and Guangdong Free Trade Zones implemented the MAH Program. In 2019, the National Medical Products Administration of China (NMPA) extended the MAH Program to: (a) the whole of Shanghai and Tianjin; and (b) 19 other cities and provinces, including Beijing, Guangdong, Jiangsu, Zhejiang, and Hunan. Over the last 18 months, the MAH Program has continued to gain traction and recognition across China, and as of the date of this publication, 21 out of 32 provinces in China have rolled out an MAH Program. Importantly, over time, the local implementation rules and practices in the different provinces and cities have become clearer.

THE MECHANICS

In summary, an MAH Program allows:

- (a) A local research and development (R&D) center to apply to be the MAH for a medical device, and in turn, nominate one or more local contract manufacturers to manufacture such medical device, without the need for the R&D center to be a qualified manufacturer; and
- (b) A foreign manufacturer to incorporate a local subsidiary to apply to be the MAH for a medical device, and in turn, nominate one or more local contract manufacturers to manufacture such medical device, without the need for such local subsidiary to be a qualified manufacturer.

This is an important development.

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KEY IMPLICATIONS

Before the MAH Program, Chinese food and drug regulators across China had implemented a system from the 1990s, whereby the MAH of a medical device must also be a manufacturer, for safety and quality assurance purposes. That meant the R&D of the medical device had to be conducted by, and the manufacturing facilities for such medical device had to be owned by, the same legal entity. Accordingly, given the manufacturing license for the medical device could only be obtained after the marketing authorization for the medical device had been approved, and accounting for the time in completing clinical trials, it would take three to five years to obtain the manufacturing approval.

In contrast, the MAH Program allows R&D functions to be performed separately from manufacturing functions, and enables the MAH of a medical device to outsource the manufacturing to a contract manufacturer, without having to go through the time-consuming process of obtaining the manufacturing approval. The average time for obtaining the marketing authorization for a Class III medical device would take roughly 15 months under the MAH Program, which is also less time consuming than the normal product registration process with the NMPA. The MAH Program also symbolizes a shift from enterprise-based regulation to product-based regulation.

MAKING USE OF THE MAH PROGRAM

A foreign medical device manufacturer can consider taking advantage of the MAH Program in structuring its market-entry for, or growing its local presence in, China's medical device industry. The general steps and commentary for doing so are set out below.

Local Incorporation

Incorporate a Chinese subsidiary within the MAH Program area.

Application to be MAH

The Chinese subsidiary can apply to become the MAH of the foreign manufactured medical device. This can be done even if the marketing authorization for the medical device has been granted to the foreign manufacturer.

Contract Manufacturing

After becoming the local MAH, the Chinese subsidiary can contract a local manufacturer to manufacture the medical device. The foreign manufacturer and the Chinese subsidiary do not have to own any manufacturing facilities in China or otherwise hold a Chinese medical device manufacturing license. However, the local contract manufacturer has to apply to the NMPA to add such medical device to the scope of its manufacturing license, and the contract manufacturing agreement has to be registered with the NMPA.

It is now also possible for the MAH to appoint a contract manufacturer outside of the place of incorporation of the Chinese subsidiary.

Sale and Distribution

As the local MAH, the Chinese subsidiary can also sell and distribute the medical devices that have been contract-manufactured locally, without separately obtaining a medical device distribution license. The Chinese subsidiary can further appoint a qualified local distributor to sell and distribute the medical devices in China.

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As the local MAH, the Chinese subsidiary is responsible for the safety and quality of the products, the after-sales services, and post-market monitoring. As such, the MAH has to maintain an appropriate number of employees.

CONCLUSION

The MAH Program is now widely seen in China as an innovative reform of China's medical device industry. There has been media coverage in China that an MAH Program can save up to 80 percent of product registration time. In February 2018, the first MAH and contract manufacturing for a Class II medical device was approved in a remarkable 26 working days from lodgment of the application.

Foreign manufacturers of medical devices have increasingly taken an interest in the MAH Program. The time and cost saving factors, coupled with the possibilities of local collaboration on manufacturing and product localization, have made the MAH Program an important consideration in strategizing a market entry, and in terms of growing local presence, in the fast-growing medical device sector in China.

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