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China's Central Government Introduces Major Policy Incentives and Restraints to the MedTech Industry

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After continuously reshaping the competitive landscape in the pharmaceutical industry for several years, the Chinese government finally shifted its attention to the medtech industry. The central government released several reform initiatives that may fundamentally affect business models and commercialization strategies for medical device companies in China. Amongst them, two of the most conspicuous initiatives include the unprecedented expansion of the medical device Market Authorization Holder (MAH) pilot program and a campaign against unreasonable pricing and overuse of high-value medical consumables. These initiatives create both opportunities and challenges to Medtech companies, especially those that historically supply high-end imported products in China.

Expansion of MAH pilot program aims to reduce capital burden for domestic innovative device companies

On August 1, 2019, China's National Medical Products Administration (the "NMPA") announced the expansion of the current medical device MAH pilot program from Shanghai, Beijing, Guangdong and Tianjin to twenty-one cities and provinces,[1] which cover most of the medical device industry footprints in China. The scale and speed of this expansion exceed the industries previous expectation. The program now allows Medtech companies to allocate R&D and manufacturing resources across pilot cities and provinces. For example, a R&D center in Shanghai can hold the regulatory approval and IP of a device while outsourcing manufacturing activities to neighboring areas that have stronger manufacturing capacity, such as Jiangsu and Zhejiang. MNCs that intend to localize their products in China, also have more flexibility to make full use of these local resources.

Extensive experience and precedents generated under this expanded program can help pave the way for the amendment of the Medical Device Regulation and full implementation of the MAH system in the future. However, it remains to be seen whether the regulators would take a more liberal approach when reviewing eligibility applications, so as to allow more companies to participate in the program.

Campaign against high-value medical consumables causes significant pricing pressure

On July 31, 2019, the PRC State Council announced a systematic and comprehensive approach to drive down high prices and overuse of high value medical consumables. Costly and widely used medical consumables with multiple suppliers will likely face the most significant impact under the new system. As drug prices become better controlled, the Chinese government will take similar measures to "clean up" the market for high value medical consumables. In doing so, the government will ultimately contain the overall health care spending and gradually substitute expensive imported consumables with locally made equivalents.

In summary, the cost containment measures include:

- *Price cuts through group purchase organizations.* The Chinese government intends to roll out a volume and category-based group purchase pilot program at public hospitals to target high value medical consumables. Pursuant to the central government's instructions, Anhui, Jiangsu and Shandong provinces have already started group purchases for selected consumables. As a result, Anhui claims it has successfully reduced the price of orthopedic implants by 53.4% on average and reduced the price of intraocular lenses by 20.5% on average. Similarly, Jiangsu claims it successfully reduced the price of cardiovascular stents by 51.01 % on average and

[1] 21 cities and provinces include Beijing, Tianjin, Hebei, Liaoning, Heilongjiang, Shanghai, Jiangsu, Zhejiang, Anhui, Fujian, Shandong, Henan, Hubei, Hunan, Guangdong, Guangxi, Hainan, Chongqing, Sichuan, Yunnan and Shanxi.

the price of pacemakers by 15.86% on average. To reinforce these efforts, the Chinese government plans to vigilantly monitor pricing and procurement information of high value consumables nationwide, which would leave little room for price manipulation. Over the next few years, these group purchasing efforts are anticipated to become the "new norm."

- *Discipline public hospitals and physicians.* The Chinese government urges all public hospitals to remove price markups of high value medical consumables by the end of 2019. If this occurs, public hospitals can no longer profit from selling consumables to patients. Public hospitals are required to actively oversee their physicians' medical practices and supervise clinical uses of high value medical consumables. In addition to internal disciplines, both hospitals and physicians will face intensive external enforcement actions against misconducts that are associated with overuse of high value medical consumables, including commercial bribery and unfair competition-related enforcement actions.

- *Curbing price increase by medical reimbursement.* The National Healthcare Security Administration (NHSA) will now play a crucial role in controlling the price of high value medical consumables. It will negotiate the purchase prices and reimbursement standards for high value consumables that wish to be listed in the national Basic Medical Insurance reimbursement scheme. In the long term, the NHSA intends to gradually introduce a DGR (Diagnosis-Related Group) payment system so that hospitals and physicians will have incentives to use low price consumables and save medical spending.

- *Building a transparent supply chain.* The Chinese government aims to gradually build up a transparent and traceable system to efficiently regulate a device during its lifespan. For this purpose, it plans to roll out the UDI (Unique Device Identification) system and standardize the bidding classifications and codes of high value consumables by the end of 2020. These measures will help local governments group together diversified consumables and oversee the supply chain, which in turn, will enhance the regulators' ability of price surveillance and quality control.

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Medtech companies should proactively review their near-term and long-term business models and strategies to respond to new opportunities and challenges in the marketplace. Multinational companies in particular will need to prepare for significant price erosion and competition from Chinese peers if their product portfolios consist primarily of mature products. In this regard, learning how to take advantage of the MAH pilot program becomes a more relevant and timely demand. On the other hand, multinational device companies may need to consider introducing more innovative and proprietary product lines in and to China in order to more effectively fence off local competition. While these innovative products will not be immediately subject to group purchase, over time, they may be affected by NHSA-led price negotiations.