

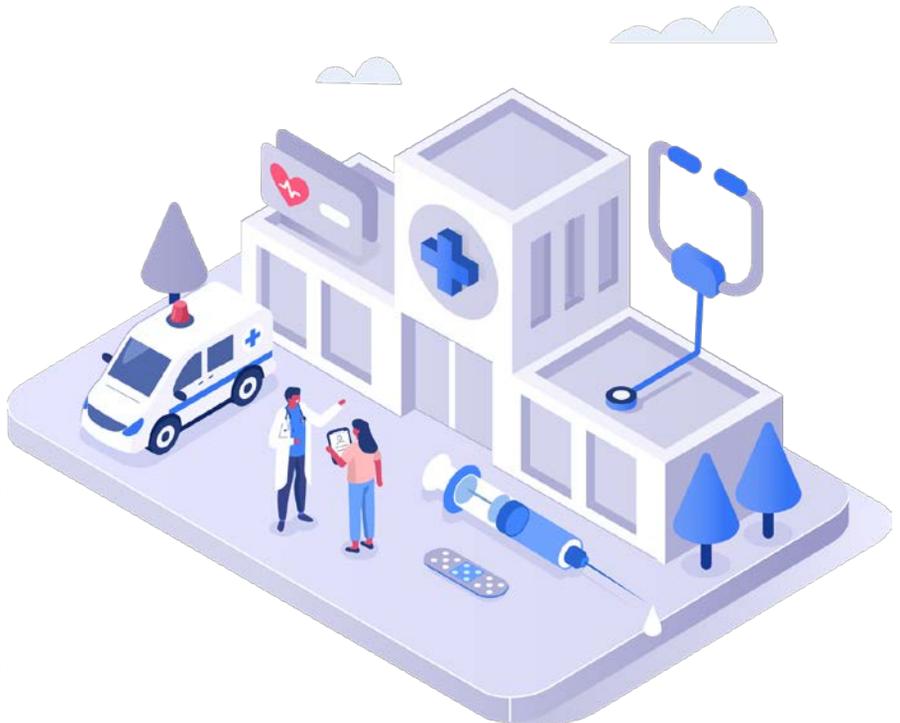


# How to cope with the Volume-based Procurement policy on high-value medical device?

**(Tax Considerations)**

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# Introduction

The Chinese government has launched radical national reforms on centralizing drug procurement, and the reform has shown initial success in driving huge price reductions. The next stage of the reform has been targeted at high-value medical device, demonstrating the government's ambition in improving the accessibility and affordability of universal healthcare in China.

Basically, the Volume-based Procurement ("VBP") policy aims to achieve a lower price through large-volume procurement, to realise the so called "volume for price" strategy. In November 2020, the central government of PRC-led and initiated a VBP of coronary stents, as the starting point of national VBP on the high-value medical device. The program intends to buy 1.07 million coronary stents starting from the year of 2021, of which the amount constitutes nearly 70% of the total consumed coronary stents in 2019. Ten varieties of coronary stents from eight companies won the bidding, including two American companies (Boston Scientific and Medtronic) and six Chinese companies. The average winning price of the respective products under this program showed more than 90% reduction compared with their previous market prices.

In terms of VBP implemented on a regional level, a number of programs have already been launched, mainly covering vascular interventions, orthopedic implants and ophthalmic materials. Up to November 22, 2020, 6 programs organized by cross-provincial league are completed or on-going, and over 40 programs organized by provincial or municipal government are completed or under way. These programs saw initial success in reduction of average market price by about 60%.

(\*Data source: Tianjin Medical Procurement Center and other provincial procurement centers for drug & medical device, for reference purpose only)



# Analysis of Industry Development Trends

The implementation of VBP for high-value medical device may be rolled out to different products over an extended period due to special characteristics of the business, such as the lack of standardization between the products. However, the Chinese government is taking actions in formulating long-term mechanism in the healthcare sector and reinforcing the promotion of relevant policies (including VBP). One example is the “two-invoices system” (“TIS”) policy on medical device. TIS refers to the policy where only up to two invoices are allowed to be issued along the chain of pharmaceutical/medical device product distribution, with one issued by the product manufacturer or general importer and the other issued by the distributor to the healthcare service providers. Compared with the pre-reform procurement model, TIS eliminates multiple layers of distributors, and significantly streamlines the distribution process. The National Development and Reform Commissions, the Ministry of Finance and other four government authorities jointly released a notice (Guoweitigaifa [2018] No.4) to encourage a roll-out of TIS policy on medical device in 2018, after which the policy has been locally adopted among various provinces and municipals successively. Besides, from a supervision perspective, the State Council of the PRC passed the "Regulations on the Supervision and Administration of Medical Device (Revised Draft)" in December 2020, aiming to establish a system of Marketing Authorization

Holder (“MAH”) in the medical device sector. In the same year, the State Food and Drug Administration of the PRC brought forward more specific regulatory requirements for the production of imported medical device in domestic enterprises.

Following the aforementioned policies, key stakeholders involved in the manufacturing and distribution of medical device should consider how to adapt in such dynamic policy environment. In this regard, we would like to share our insights with an analysis of the industry development trends for those medical device companies, meanwhile contributing to their overall business planning as well as tax efficiency improvement. Hereby we’ve listed some short-term and long-term strategic considerations:





## Short-term Considerations

1. The company should consider the following measures, such as optimize the layout of product lines, accelerate product upgrade or innovation, and launch products which better meet the VBP requirements, in order to help achieving product differentiation, boost the revenue growth and enhance the risk control capabilities of the enterprises.
2. The improvement of overall cost control, including taxes, is important in formulating the competitive advantage under VBP bidding. For example, negotiation of lower import price, or consider applying for the applicable tariff preferential treatment to reduce the tariff, may achieve reduction of the procurement cost in the short term.



## Medium and Long-term Considerations

3. Under the foreign investment policy of Chinese government, investment in manufacturing of pharmaceutical and innovative medical device and equipment has been encouraged for many years. The company may consider manufacturing of certain product lines in China, as an alternative to importation. As part of the study, a full-scope location study covering local government policies, tax incentives and other support would be recommended. Further, the localized production could help to streamline the supply chain and establish the economies of scale, which will contribute to the success of cost control.
4. Moreover, the company may adopt more dynamic marketing and promotion approaches, such as joint promotion, and cooperation with Contract Sales Organizations ("CSOs"). In particular, you should pay attention to the tax and compliance challenges brought by CSOs.

# How KPMG Can Support

To cope with the radical changes under VBP, multi-national medical device companies (“MNCs”) should review its strategies from short and long term perspectives and look for new growth opportunities. KPMG has a specialised team with not only tax but also

industry knowledge to support you in the development and implementation of your strategy. We could be of assistance in many ways, including but not limited to compliance, legal and tax perspectives (including transfer pricing and customs).



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KPMG can work with companies from a strategic view and contributing to formulating important business decisions, including tax planning and implementation assistance. For instance, influenced by the VBP policy, it is very likely that the Chinese subsidiary which originally carried out limited functions and risks would experience a dramatic drop in profit margin, which may deviate from the target profit margin set by the group. Under such circumstances, MNCs should take various measures to restore the profit margin. On one hand, compensations based on the transfer pricing policy are probably needed. Such compensations could be helpful in the short term, however, may trigger some long-term issues, e.g. how to re-define the roles of domestic enterprises to match with its functions and risks. Moreover, since the sales prices are reduced under the VBP program, domestic enterprises should also carry out further analysis on the rationality of adjusted import prices, and prepare relevant documents to support the pricing policy, targeted profit margin as well as the profit margin distribution at a product level.

2



In the short term, since the domestic sales price would drop significantly due to VBP , import prices should be reasonably adjusted if the Chinese subsidiary of an MNC still relies on importing products from overseas entities. As such, domestic enterprises are suggested to negotiate the purchase prices with group suppliers to cut down the import costs. In this regard, importers need to prepare explanatory documents in advance to support a reasonable price reduction of import products, so as to obtain support from the customs and facilitate the customs clearance process. Besides, enterprises may also consider leveraging preferential policies to further reduce the import costs, for example, applying for tariff adjustments through participating in the tax policy investigation, adding temporary tax rate or utilizing the preferential tariffs of free trade agreements to lower the tariffs on imported medical device.

3



KPMG has rich experience in tax planning to support the business operations of multinational medical device enterprises in China. Since many local governments hold a positive attitude towards foreign investments, MNCs in medical device industry should seize the opportunity to consider its localization strategy. We can assist in the feasibility study and formulate a set of planning ideas for management's further considerations. Our insights will help with the relevant decisions in manufacturing site location, set-up cost, time duration, and relevant tax implications. Notably, the site location is of crucial importance at the planning stage. Apart from sorting out different preferential tax policies and subsidies, we will compare and contrast the applicable tax incentive policies in each case. Recently, we observed a local government in a coastal region offer a reduced corporate income tax rate of 15% (i.e. lower than the standard corporate income tax rate of 25%) to those qualified biotech and medical device companies. Besides, more measures could be adopted in improving tax efficiency, such as applying for high-tech enterprise qualifications and utilizing the R&D super deduction policies. These policies could significantly enhance the return on investment for overseas investors. Additionally, for the potential business arrangement with the CSOs, the potential risks from both tax and compliance perspectives shall be noticed and quantified for management's consideration.

Given the dynamic international relations as well as the fast-changing domestic industry policies, we would suggest that enterprises in the PRC make an early assessment to embrace the changes as well opportunities. Proactive assessment and planning will support the companies to maintain a competitive position in this dynamic market.



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