Chinese MOH Announced Centralized Procurement of High Value Medical Consumables

On December 17, 2012, the Ministry of Health ("MOH") issued the *Tentative Guidelines for Centralized Procurement of High Value Medical Consumables* (the "Guidelines") with immediate effect, with an aim to control health care costs, in particular in the area of medical consumables which are extensively used in clinical practice with high prices and strict safety requirements. Prior to the issuance of the Guidelines, the centralized procurement system had been implemented in several provinces (such as Beijing, Zhejiang, Jiangsu and Hunan) for certain High Value Medical Consumables ("HVMC"). MOH's rolling out of the centralized procurement system for HVMCs is expected to improve the transparency of healthcare institutions' procurement practices and further reduce HVMC prices.

Pursuant to the Guidelines, HVMCs to be purchased by all non-profit public healthcare institutions at the county level or above must be collectively procured online through the provincial centralized tendering and bidding agencies for pharmaceutical products every two years. Other private healthcare institutions are also encouraged to participate in the centralized procurement process.

The Guidelines set forth a reference list of HVMCs subject to the centralized procurement mechanism, including intravascular interventional devices, non-vascular interventional devices, orthopedic implants, neurosurgical implants, electrophysiological catheters, pacemakers, extracorporeal blood circuit/blood purification devices, ophthalmic implants, dental implants, artificial heart valves, and others. Each province is authorized to formulate its own list of HVMCs subject to centralized procurement.

Only HVMC manufacturers can participate in the online centralized procurement process, with the exception that distribution subsidiaries that sell a manufacturer's own products, or general distributors for imported products, may bid on behalf of manufacturers. Manufacturers with adverse records concerning their manufacturing or distribution activities in the prior three-year period are disqualified for bidding. The bidding price needs to include logistics costs, though the logistical services may be performed by the manufacturers themselves or qualified distributors. Sales contracts between the healthcare institutions and the manufacturers must use the form prepared by the MOH. If a manufacturer commits fraud, engages in commercial bribery or other unfair competition activities during the bidding process, or fails to perform its contractual obligations to supply its products, such behavior will be published online and all of the manufacturer's products will be withdrawn from the procurement list. Further, in the subsequent two years, such manufacturer will be disqualified from bidding and no healthcare institution in the relevant province will be allowed to purchase any of its products.

The evaluation criteria for each HVMC subject to centralized procurement include quality, price, and their relative ratio. Clinical efficacy, quality standards, degree of R&D and scope of application are factors to be considered when deciding the bid winners. Health economics may also be included as part of the evaluation criteria.

Each province is expected to formulate its own implementing rules following the Guidelines. HVMC manufacturers should monitor the development of provincial practices and prepare a balanced pricing strategy accordingly.

If you would like to discuss the foregoing or any other related matter, please contact <u>Katherine Wang</u> or your usual Ropes & Gray advisor.