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CFDA Amends Medical Device Recall Rules

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Recently China's Food and Drug Administration ("CFDA") released the *Provisions for Medical Device Recall ("New Recall Rules")*. The New Recall Rules, becoming effective on May 1, 2017, will replace the existing *Interim Provisions for Medical Device Recall* promulgated by the former Ministry of Health in 2011 ("*Existing Recall Rules*"). The New Recall Rules follow the basic regulatory framework for device recall provided in the Existing Recall Rules. Recalls are divided into mandatory recalls (imposed by local FDAs) and voluntary recalls (initiated by device manufacturers). Depending on the severity of product defects, recalls are classified as Level 1 recalls (products caused or may cause serious damage to health), Level 2 recalls (products caused or may cause non-lasting or reversible damage to health) or Level 3 recalls (products carry only a minor risk of causing damage to health). Under these different recall scenarios, device manufacturers are further subject to different requirements for recall implementation. Device distributors and device-using hospitals are also obligated to cooperate with or assist the manufacturers during the recalls. Compared with the Existing Recall Rules, the New Recall Rules introduced the following major changes:

Clarify the application scope of the rules and the responsible entity for recall

The New Recall Rules apply to the recall of medical devices marketed in China. For domestic products, the holder of the product's registration license is responsible for recall; for imported products, the designated regulatory agent of the foreign device manufacturer in China is responsible for recall. If a foreign manufacturer initiates a recall outside China for a product also marketed in China, its local agent must timely report the recall-related information to the CFDA.

Expand the scope of Defective Products

In the Existing Recall Rules, Defective Products (i.e., products that should be recalled) are defined as devices that pose unreasonable risk of potentially damaging human health or life safety when used under normal conditions. The New Recall Rules enlarge the existing definition by adding three more types of Defective Products: (a) products that do not conform to compulsory standards, or to the product's technical specifications registered or filed with the CFDA; (b) products that pose unreasonable risk due to the failure to comply with the applicable quality management rules for device manufacture and supply; and (c) products that for other reasons must be recalled.

More severe penalties for manufacturers that refuse to implement mandatory recalls

Local FDAs may identify, investigate and assess devices with potential defects and determine upon their own discretion that such products should be recalled. In the event of such mandatory recalls, if device manufacturers refuse to implement the recalls, the Existing Recall Rules allow the local FDAs to impose monetary fines of three times the total value of products that should be recalled. The New Recall Rules, on the other hand, refer to the penalty provisions under Article 66 of the State Council's *Regulation for the Supervision and Administration of Medical Devices* (Order 650), which allow the local FDAs to impose fines of up to ten times of the goods' value.

The Provisions for Medical Device Recall form an important part of China's new device regulatory regime centering around Order 650. Device companies with product sales or local operations in China are recommended to review the New Recall Rules and keep their post-market product safety measures in line with the more stringent regulatory requirements.

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