China: State Council Revises Regulations on the Supervision and Administration over Medical Devices

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On March 7, 2014, State Council promulgated the revised Regulations on the Supervision and Administration over Medical Devices (the Regulations), which became effective June 1, 2014. Compared to its prior version, the Regulations introduce several major changes as summarized below.

**Reclassification of Medical Devices by Risk Levels**

The Regulations re-classify the medical devices based on their risk levels to include the following three classes:

- **Class I medical devices**, which refer to those devices with low risks whose safety and effectiveness can be ensured through routine administration;

- **Class II medical devices**, which refer to those devices with moderate risks whose safety and effectiveness needs to be ensured by strict control and administration; and

- **Class III medical devices**, which refer to those devices with relatively high risks whose safety and effectiveness needs to be ensured by taking special measures to exert strict control and administration.

**Changes for Registration and Filing Procedures**

- Compared to previous practice that all the medical devices are subject to registration procedures, according to the Regulations, Class I medical devices are subject to filing procedures only, while Class II and Class III medical devices will continue to be subject to registration procedures.

- The medical device registration certificate is valid for five years, one year longer than the previous standard.

**Stricter Supervision System over Medical Devices**

- The Regulations provide that the country shall set up a monitoring system over the medical devices to timely collect, analyze, evaluate and control the adverse events of the medical devices.

- The manufacturer of medical devices is required to set up a quality management system that is compatible to the standards of medical devices produced, and carry out self-inspection over the quality management system on a regular basis and report the self-inspection results to the competent provincial or local food and drug supervision and administration authority.

**Manufacturer’s Obligations to Recall Defective Medical Devices**

- If the manufacturer of medical devices finds that the medical devices produced by it do not meet the statutory standards, the products’ technical requirements or have other defects (the Defective Medical Devices), it is required to (a) immediately stop the production of the Defective Medical Devices, (b) inform
the distributors, users and consumers to stop its business and use of the Defective Medical Devices, (c) recall the Defective Medical Devices that have entered into the market, and (d) take remedial measures or destroy the Defective Medical Devices. Such manufacturer is also required to report the results of its recall and handling efforts to the food and drug supervision and administration authority and the competent health and family planning authority.

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