ROPES & GRAY

ALERT

China Life Sciences

June 29, 2018

China's MOJ Solicits Comments on Amendment to Medical Device Regulations

Attorneys
Katherine Wang

The PRC Ministry of Justice recently published a comprehensive draft amendment ("Draft Amendment") outlining the proposed revisions to the current Medical Device Regulations (MDR, previously known as the State Council Order # 650). The Draft Amendment is now ready for public comments until July 24, 2018.

This Draft Amendment updated a previous draft amendment[1] ("2017 Draft") issued by the former China Food and Drug Administration in last October. Several regulatory reform initiatives announced by China's State Council were formally included in the Draft Amendment, e.g., compassionate use (or expanded access) of devices that treat life-threatening diseases without any effective cures, and conditional approvals for devices treating rare diseases, life-threatening diseases that do not have any effective cures, and public health emergencies.

In addition, the Draft Amendment introduces some noteworthy changes to the 2017 Draft:

1. **Refine the Marketing Authorization Holder (MAH) Regime**: The Draft Amendment refines the legislative structure of the 2017 Draft to adapt to the MAH framework. For example, the Draft Amendment creates a new provision listing the MAH's statutory obligations. Also, the Draft Amendment clarifies that MAH can distribute devices they own without obtaining a separate device distribution approval/recordal or a GSP certificate.

2. **Simplify the Clinical Evidence Requirements**: The current MDR requires Medtech companies to either conduct clinical studies in China or submit clinical evaluation reports illustrating equivalence to previously approved products of the same type to show safety and effectiveness. These requirements create considerable challenges for time to market. The Draft Amendment provides a favorable response to the industry by allowing Medtech companies to submit foreign clinical study data in lieu of China study data. China studies are only required for products that are high risks or support or maintain life, and the clinical trial authorizations are deemed issued after 60 days from the date of IDE filing in the absence of a rejection or deficiency notice. Furthermore, clinical evaluation is only mandatory for Class 3 devices.

3. **Reinforce Post-Approval Compliance Obligations**: The Draft Amendment provides that the China National Drug Administration (CNDA), the provincial drug administration and the local administration for market regulation would be responsible for GCP, GMP and GSP enforcement, respectively. Overseas inspections will be organized by the CNDA. While the 2017 Draft already enhanced the penalties for non-compliance, the Draft Amendment introduces more rigorous sanctions. The manufacture and distribution of "disguised medical devices,"[2] a new term created by the Draft Amendment, can lead to fines in the range of 15 to 30 times the sales value. For other types of non-compliance, the amount of fines is also increased.

[1] See our Alert dated Nov 1, 2017.

[2] Disguised medical devices are defined as follows: (a) an unapproved device; (b) a non-device that is claimed to be a device; (c) a device that is approved based on misrepresentation or falsified information; (d) a device that is in reliance of a forged regulatory approval.

4. **Consolidate the Approval Authority for Class 2 Devices**: The Draft Amendment intends to remove the provincial drug administration's review and approval authority for Class 2 devices, and transfer such authority to the CNDA. The CNDA would be authorized to delegate the approval authority to certified review and approval agencies.

5. **Prohibit the Importation and Distribution of Used Devices**: The Draft Amendment proposes to add a provision that explicitly prohibits the importation and distribution of used devices.

6. **Add the Unique Device Identification Requirement**: The Draft Amendment proposes to add a provision that requires all medical devices to bear a Unique Device Identification.

7. **Ease Control over the Distribution of Certain Class II Devices**: The current MDR requires distributors of Class 2 devices to file for a record with the local drug administration. The Draft Amendment intends to further simplify regulatory control over the distribution of Class 2 devices if such devices do not pose considerable risks. The CNDA will publish a catalogue of Class II devices that can be exempted from the record filing requirement.

The Draft Amendment, once approved by the State Council, will significantly impact the Medtech industry in China. We strongly encourage Medtech companies to submit comments before the deadline, and closely monitor the legislative progress.

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