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ALERT

China Life Sciences

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China FDA's Device Regulations Ready for Public Comments

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The China Food and Drug Administration (CFDA) has published its proposed amendment of the Medical Device Regulations (MDR), previously known as the State Council Order # 650, for public comments. This Alert summarizes the key changes.

The proposed MDR amendment aims at implementing the central government's reform. It does not entail structural changes, but reflects a fundamental shift of the regulatory philosophy. Compared with the current MDR, which emphasizes pre-approval administration, the amendment strengthens post-approval compliance obligations (e.g., re-evaluation, device safety monitoring, voluntary recalls, etc.). It adds nine new articles and revises 19 articles. The changes are consistent with the following principles previously announced in the central government's policy:

1. The Marketing Authorization Holder (MAH) system will be implemented in the device sector. MAHs will be responsible for the liabilities related to pre-clinical research, clinical studies, manufacturing, distribution, adverse events reporting and product recalls. Foreign MAHs will need to appoint a domestic agent, who can perform the same post-market responsibilities as domestic MAHs and be jointly liable with the foreign MAHs for product quality and services issues.

2. The Country of Origin Certificate (COO) issue is partially resolved. Foreign manufacturers seeking approval for innovative imported devices that will be launched first in China will not need to present the COO at the time of filing. Nevertheless, COO is still required for the issuance of import device permits if the products are not deemed innovative as per the CFDA regulation.

3. Clinical trial authorizations (CTA) for certain high-risk devices will be deemed issued if no rejection or deficiency notice was issued within 60 working days from the date of acceptance. Clinical study sites will be qualified by record-filing; no certification by the CFDA and the National Health and Family Planning Commission will be required.

4. Conditional approvals will be made available for devices treating rare diseases, critical diseases that do not have an effective treatment method, or responding to abrupt public health incidents.

5. Foreign clinical study data can be used in marketing authorization applications in China if it meets the CFDA requirements.

6. Expanded access of investigational devices will be made available for patients in the clinical study sites upon their giving informed consent, provided that the investigational devices are used for critical, life-threatening diseases without an effective treatment method and can confer benefits to patients based on preliminary study data.

7. Type testing will be significantly simplified. Companies can use their own testing reports or reports issued by qualified third-party testing labs in place of type-testing reports issued by the CFDA-designated testing centers.

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8. Reselling pre-owned medical devices by distributors will be prohibited under the amendment. Violations can lead to fines of five to 10 times the sales value.

It is worth noting that the CFDA plans to impose personal liabilities on individuals who breach the various compliance obligations. Executives and responsible staff of MAHs, manufacturers, distributors and health care institutions will be liable for fines ranging from 30-100% of their annual income if their employers violate the law deliberately or the act of non-compliance causes highly negative impact.

MedTech companies are advised to carefully review the proposed amendments and submit their comments by November 12, 2017. The amendment, once implemented, will provide a more innovation-conducive environment for MedTech companies, both at home and abroad. It will also urge MedTech companies to revisit their quality management systems and be prepared for the intensifying post-approval enforcement.

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

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