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ALERT

China Life Sciences

December 20, 2016

China Solicits Comments on Drug GCP

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The China Food and Drug Administration ("CFDA") recently proposed revisions to the Good Clinical Practices for Pharmaceuticals ("GCP"), the most comprehensive revision in 13 years. The revisions ("Revisions") are now open to public comments until January 31, 2017.

It's notable that the Revisions have rewritten all the articles of the current GCP, but these sweeping changes are not especially innovative, as most of the concepts and principles have already been addressed in the International Conference on Harmonisation ("ICH") GCP.

Overall, the Revisions set forth general principles of conducting clinical studies in China, as well as guidance of roles and responsibilities for the ethics committee ("EC"), the investigator and the sponsor, as well as the requirements for protocol and investigator's brochure ("IB"). Highlights of the changes proposed in the Revisions are as follows:

- **Regulate the Handling and Retention of Biological Specimens:** According to the Revisions, the sponsor shall be prohibited from conducting any testing that is unrelated to the study protocol approved by the EC on biological specimens. Additionally, the Revisions would require the sponsor to seek written consent from the subjects regarding the continuous storage of and/or possible use in any future research of leftover biological specimens after completion of the trial. The consent form would have to specify issues such as the retention period, the data confidentiality requirements, and the circumstances under which the data and specimens could be shared with other investigators.

- **Extend Insurance Coverage to Institutions:** Unlike the current GCP, the Revisions would require the sponsor to insure or indemnify both the investigator and the institution against all claims, except for those arising from malpractice.

- **Allow an Individual to Serve as Sponsor or CRO:** As a response to the pilot program of marketing authorization holder promulgated by the State Council this past June, the Revisions would allow individuals to act as sponsors and contract research organizations ("CROs").

- **Specify the Requirement and Quantity of Retention Samples:** Under the Revisions, reserve samples of study drugs for bioequivalence and bioavailability testing must be retained at the study site for no less than two years after marketing approval. The investigator will randomly select the reserve samples from the supply sent by the sponsor and should retain enough to allow five rounds of quality standard testing.

- **Detail the Process of Seeking Informed Consent from Subjects:** Under the Revisions, the EC would have to pre-approve any new information that may affect subjects' willingness to participate in the study. Importantly, the Revisions would prohibit agreements (whether oral or written) that ask subjects to waive their legal rights, or that may release the investigator, the institution, the sponsor, or its agents from liability.

- **Add Notification Requirement of the Unblinding Results:** The Revisions propose that, for any double-blinding studies, the sponsor must provide the investigator and all study participants with the treatment allocation status after unblinding.

- **Revise the Data Retention Requirement:** Whilst the current GCP imposes different data retention requirements on the investigator (e.g., five years after the study ends) and the sponsor (e.g., five years after obtaining marketing approval), the Revisions would impose similar obligations on both: data would have to be retained for two years after marketing approval or for five years after the study ends.

- **Require to Specify Direct Access to Source Records:** The Revisions would require that under either the protocol or the clinical trial agreement ("CTA"), the investigator and the institution must be required to give the monitors and auditors direct access to the source data and source documents related to the clinical trial. This change may help clarify the industry's concern regarding who may have access to subjects' medical records to verify the authenticity of the study data, especially for the clinical trial data inspection campaign.

- **Clarify Contractual Arrangements Regarding CTA:** The Revisions clearly stipulate that a CTA shall be structured as a three-party agreement between the sponsor, the investigator and the institution. Each party shall sign the CTA on his/her own capacity. In addition, for multi-center trials, the Revisions specify that the sponsor shall sign the CTA with all participating investigators and the relevant institutions.

- **Impose Regular Review Requirement of IB:** The requirement regarding the IB in the current GCP is simple and general. The Revisions would incorporate the same detailed regulatory requirement on IB as that provided in the ICH GCP. In particular, according to the Revisions the sponsor must establish a written procedure regarding amendments to the IB, noting that the IB needs to undergo a review and amendment at least once per year. In addition, the Revisions add several provisions to set forth the purpose, general considerations, and contents regarding the IB.

- **Adopt Some Changes Reflected in the Latest ICH GCP:** The latest version of the ICH GCP, the E6 (R2), was adopted by the ICH on November 9, 2016. Accordingly, the Revisions include a number of the new changes reflected in the E6 (R2), such as the notions of certified copies and validation of computerized systems, as well as the sections regarding quality management, risk management, oversight of CROs, and risk-based monitoring, among others. To some extent, it reflects CFDA's willingness to establish a regulatory framework in line with international standards.

The Revisions would standardize the conduct of drug studies in China, as well as strengthen the management of such studies. It remains unclear whether and when these changes will be adopted. We recommend that pharmaceutical companies closely monitor the progress of the Revisions and propose their comments by the deadline.

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