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E-ALERT | Food & Drug

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CFDA PUBLISHES NOTICE ON MANDATORY CLINICAL TRIAL DISCLOSURES

The China Food and Drug Administration (CFDA) issued a notice on September 6, 2013, requiring that drug manufacturers register and publish information about their clinical trials on an online platform. Sponsors must provide the registration information by December 6, 2013 for existing clinical trials and within one month of approval of any new clinical trials. Failure to meet these clinical trial disclosure requirements will result in CFDA's refusal to communicate with the sponsor and the revocation of clinical trial approvals granted after the notice date. Due to these serious consequences, all drug manufacturers conducting clinical trials in China must understand and comply with these new requirements.

The notice does not appear to have been released for public comment, and it is not implementing a prior rule. Rather, the notice's origins appear to be something of a mystery. The notice appears to be a guidance document (often referred to as a normative document), but on the basis of past practice and recently issued CFDA regulations on rulemaking, it has binding force on industry.

The notice also does not specify pursuant to what authority CFDA is acting, but CFDA has general authority to regulate clinical trials under the Drug Administration Law and related regulations. For example, CFDA or local provincial FDAs approve drug and medical device clinical trials. CFDA also supervises the implementation of Good Clinical Practices. CFDA noted in the introduction to the notice that it was "referencing" World Health Organization requirements and international practice in creating this requirement.

This is not the first time that China has experimented with putting clinical trial information online. CFDA's Center for Drug Evaluation (CDE) has already established a website for voluntary registration of clinical trials. However, this is the first time that CFDA is mandating registration.

According to the notice, this new requirement seeks to strengthen the regulation of clinical trials, advance the transparency of clinical trial information, and protect the rights and privacy of clinical trial subjects. The notice addresses three issues: (1) the scope and content of the clinical trial disclosure, (2) the requirement for clinical trials to be disclosed, and (3) the procedures for submitting information to the online platform for clinical trial disclosures.

The registration and disclosure requirement applies to any clinical trials conducted in China, including bioequivalence studies, pharmacokinetics studies, and Phase I-IV clinical trials. The registrations must include the information and materials provided by the sponsor under the Drug Registration Regulations, which set forth the requirements for clinical trial application and approval. This information includes, inter alia, the clinical trial protocol, information about the sponsors and investigators, and an ethics committee approval letter. Not all of the information filed, however, will be made public. Instead, CFDA indicates that some information will be made publicly available and the rest will be accessible to CFDA only for regulatory purposes, as explained in the Drug Clinical Trial Registration Instructions, available on the online platform. The notice also includes a brief reference to updating the registration when appropriate.

For new clinical trials, the sponsor must complete the initial registration of a clinical trial and obtain a unique registration number within one month of the approval of their clinical trial application. Before enrolling the first study subject, the sponsor must complete (1) the full registration and (2) the submission for initial public disclosure. If the sponsor fails to complete its submission for initial public disclosure within a year of the approval of the clinical trial application, the sponsor must provide an explanation for its lateness. If the sponsor fails to complete the submission for initial public disclosure within three years of the approval of its clinical trial application, then the trial's approval will automatically expire.

For clinical trials that are currently active and ongoing, a sponsor must complete the information registration within three months of the notice's publication – that is by December 6, 2013. The notice does not state whether trials that have already been completed must register. Once registered, the clinical trials will appear in an online platform run by CDE called www.chinadrugtrials.org.cn.

CFDA's notice provides no information regarding the disclosure of clinical trial results on the online platform. Instead, the notice simply provides a general statement, with no details, that drug clinical trial registration and public disclosure of registration information will be "linked" to the "technical evaluation and supervision and investigation" of drug products. The notice also suggests that the online platform will promote the public's understanding and supervision of clinical trials.

Clinical trial disclosure has posed a significant issue in other parts of the world. Many countries around the world already have in place requirements for registration of clinical trials, as well as posting of results information on publicly available websites. US law, for example, requires publication of results data, in tabular form, for most clinical trials other than Phase I clinical trials. Some regulatory authorities have sought to go further and disclose substantial portions of the underlying clinical trial documents (e.g., clinical study reports) or even raw patient data with minimal redactions. These developments have caused industry stakeholders to raise concerns relating to the release of confidential commercial information.

Sponsors of clinical trials in China should closely monitor these types of developments in China to observe whether similar requirements and concerns will arise. The CFDA notice explains that the online platform will be in tentative operation for one year starting from the notice date and will be managed by CDE. CDE will make adjustments to the content requirements and instructions for use during the tentative operation.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

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